

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

**EP 1 048 317 A2**

(12)

**EUROPEAN PATENT APPLICATION**

(43) Date of publication:  
02.11.2000 Bulletin 2000/44

(51) Int. Cl.<sup>7</sup>: **A61N 1/05, A61N 1/34**

(21) Application number: **00107043.2**

(22) Date of filing: **03.04.2000**

(84) Designated Contracting States:  
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE**  
Designated Extension States:  
**AL LT LV MK RO SI**

(30) Priority: **30.04.1999 US 303145**

(71) Applicant: **MEDTRONIC, INC.**  
**Minneapolis, Minnesota 55432-3576 (US)**

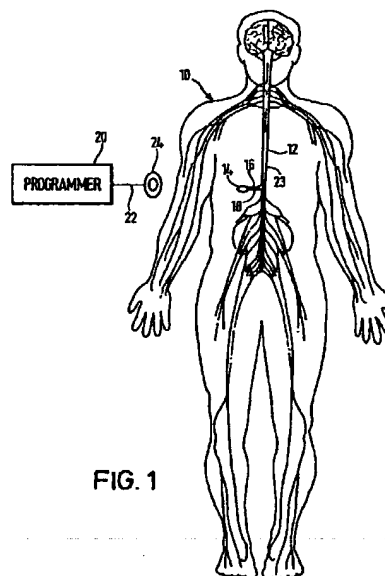
(72) Inventors:  
• **Gielen, Frans**  
**6251 NE Eckelrade (NL)**  
• **King, Gary W.**  
**Fridley, Minnesota 55432 (US)**

• **Petersen, Daryle**  
**Minneapolis, Minnesota 55421 (US)**  
• **Rise, Mark T.**  
**Monticello, Minnesota 55362 (US)**  
• **Schendel, Michael**  
**Andover, Minnesota 55304 (US)**  
• **Starkebaum, Warren**  
**Plymouth, Minnesota 55441 (US)**

(74) Representative:  
**Hughes, Andrea Michelle**  
**Frank B. Dehn & Co.,**  
**European Patent Attorneys,**  
**179 Queen Victoria Street**  
**London EC4V 4EL (GB)**

**(54) Systems for positioning therapy delivery elements within a spinal cord or a brain**

(57) The present invention addresses the problems associated with lead migration, patient movement or position, histological changes, neural plasticity or disease progression. The present invention discloses techniques for implanting a lead having therapy delivery elements, such as electrodes or drug delivery ports, within a vertebral or cranial bone so as to maintain these elements in a fixed position relative to a desired treatment site. The therapy delivery elements may thereafter be adjusted in situ with a position control mechanism and/or a position controller to improve the desired treatment therapy. The present invention also discloses techniques for non-invasively positioning and re-positioning therapy delivery elements after implant to provide electrical stimulation and/or drug infusion to a precise target. A position control mechanism and/or a position controller are provided for adjusting in situ the position of the therapy delivery elements relative to the targeted tissue of interest. The therapy delivery elements may be positioned laterally in any direction relative to the targeted treatment site or toward or away from the targeted treatment site. A control system may be provided for open- or closed-loop feedback control of the position of the therapy delivery elements as well as other aspects of the treatment therapy.



**FIG. 1**

**EP 1 048 317 A2**

## Description

**[0001]** The present invention relates to stimulation or drug delivery systems, and more particularly relates to systems for positioning the treatment therapy elements, such as electrodes or catheters, to provide more effective treatment therapy.

**[0002]** Electrical stimulation techniques have become increasingly popular for treatment of pain and various neurological disorders. Typically, an electrical lead having one or more electrodes is implanted near a specific site in the brain or spinal cord of a patient. The lead is coupled to a signal generator which delivers electrical energy through the electrodes to nearby neurons and neural tissue. The electrical energy delivered through the electrodes creates an electrical field causing excitation of the nearby neurons to directly or indirectly treat the pain or neurological disorder.

**[0003]** Presently, only highly skilled and experienced practitioners are able to position a stimulation lead in such a way that the desired overlap between stimulation sites and target tissue is reached and desired results are obtained over time with minimal side effects. It requires much time and effort to focus the stimulation on the desired body region during surgery. These leads cannot be moved by the physician without requiring a second surgery.

**[0004]** The major practical problem with these systems is that even if the paresthesia (sensation of stimulation) location covers the pain area perfectly during surgery, the required paresthesia pattern often changes later due to lead migration, histological changes (such as the growth of connective tissue around the stimulation electrode), neural plasticity or disease progression. As a result, the electrical energy may stimulate undesired portions of the brain or spinal cord.

**[0005]** Maintaining the lead in a fixed position and in proximity to the treatment site is therefore highly desirable. Presently known systems are susceptible to lead migration. Accordingly, the lead may migrate such that the targeted tissue is outside of the effective steerable treatment range of the lead. Additionally, for some treatment applications, the lead just cannot be placed optimally to provide the desired treatment therapy. For example, in the case of treatment of lower back pain, electrical stimulation may be provided at the middle thoracic vertebral segments, T6-T9. With currently available systems, this often fails mostly due to the great thickness of the cerebral spinal fluid (CSF) layer.

**[0006]** Alternatively, it is desirable to redirect paresthesia without requiring a second surgery to account for lead migration, histological changes, neural plasticity or disease progression. With present single channel approaches, however, it is difficult to redirect paresthesia afterwards, even though limited readjustments can be made by selecting a different contact combination, pulse rate, pulse width or voltage. These problems are found not only with spinal cord stimulation (SCS), but

also with peripheral nerve stimulation (PNS), depth brain stimulation (DBS), cortical stimulation and also muscle or cardiac stimulation. Similar problems and limitations are present in drug infusion systems.

**[0007]** Recent advances in this technology have allowed the treating physician or the patient to steer the electrical energy delivered by the electrodes once they have been implanted within the patient. For example, U.S. Patent No. 5,713,922 entitled "Techniques for Adjusting the Locus of Excitation of Neural Tissue in the Spinal Cord or Brain," issued on February 3, 1998 to and assigned to Medtronic, Inc. discloses one such example of a steerable electrical energy. Other techniques are disclosed in Application Serial Nos. 08/814,432 (filed March 10, 1997) and 09/024,162 (filed February 17, 1998). Changing the electric field distribution changes the distribution of neurons recruited during a stimulus output, and thus provides the treating physician or the patient the opportunity to alter the physiological response to the stimulation. The steerability of the electric field allows the user to selectively activate different groups of nerve cells without physically moving the lead or electrodes.

**[0008]** These systems, however, are limiting in that the steerable electric field is limited by the location of the electrodes. If the electrodes move outside of the desired treatment area or if the desired stimulation area is different due to histological changes or disease migration, the desired treatment area may not be reached even by these steerable electrodes. Further, even if these steerable electrodes may be able to stimulate the desired neural tissue, the distance from the electrodes to the tissue may be too large such that it would require greater electrical power to provide the desired therapy. It has been shown that only a fraction of the current from modern stimulation devices gets to the neurons of interest. See W.A. Wesselink et al. "Analysis of Current Density and Related Parameters in Spinal Cord Stimulation," IEEE Transactions on Rehabilitation Engineering, Vol. 6, pp. 200-207 (1998). This not only more rapidly depletes the energy reserve, but it also may stimulate undesired neural tissue areas thereby creating undesired side effects such as pain, motor affects or discomfort to the patient.

**[0009]** In short, there remains a need in the art to provide an electrical stimulation device that is not susceptible to lead migration and that may be positioned in proximity to the treatment site. In addition, there remains a need in the art to provide an electrical stimulation device that may be adjusted to account for lead migration, patient movement or position, histological changes, and disease migration.

**[0010]** As explained in more detail below, the present invention overcomes the above-noted and other shortcomings of known electrical stimulation and drug delivery techniques. The present invention, according to one aspect, provides a system for providing treatment therapy to targeted tissue comprising in combination:

- (a) a therapy delivery device;
- (b) at least one therapy delivery element coupled to the therapy delivery device for providing treatment therapy to the targeted tissue; and
- (c) at least one position control mechanism coupled to at least one of the therapy delivery elements for adjusting, at any time after implanting the therapy delivery elements, the position of the therapy delivery element relative to the targeted tissue.

**[0011]** The position may be adjusted laterally in any number of directions relative to the lead or toward or away from the excitable tissue of interest. Any number of position control mechanisms may be incorporated to selectively adjust the position of the therapy delivery elements. Also, a position controller such as a micro-processor may be utilized to operate the position control mechanism to position the therapy delivery elements.

**[0012]** According to another aspect, there is provided an implantable lead for providing therapy to a body comprising:

- (a) an elongate central portion;
- (b) at least one extendable member having an end, the extendable member depending from the central portion and being adapted to assume a compact position, in which the end is disposed in close proximity to the central portion, and an extended position, in which the extendable member is disposed removed from the central portion; and
- (c) at least one therapy delivery element disposed on the extendable member for delivering therapy to the body.

**[0013]** According to another aspect, there is provided a system for providing neurostimulation therapy to targeted tissue comprising in combination:

- (a) a signal generator;
- (b) at least one housing member implantable within a bone near the targeted tissue and adjustable relative to the bone; and
- (c) at least one electrode coupled to said signal generator and attached to a distal end of the housing member for providing electrical stimulation to the targeted tissue.

**[0014]** According to another aspect, there is provided an implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising:

- (a) a middle portion having at least one central therapy delivery element on a ventral side;
- (b) at least two end portions, each end portion having at least one end therapy delivery element on the ventral side; and
- (c) means capable of expanding the middle portion such that the central therapy delivery element is

positioned away from a dorsal side of the lead.

**[0015]** According to another aspect, there is provided an implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising:

- (a) a ventral side having at least one therapy delivery element;
- (b) a dorsal side opposite the ventral side;
- (c) at least one balloon-like member attached to the back side of the lead, the balloon-like member capable of expanding by receiving a fluid, whereby expansion of the balloon-like member resulting in positioning at least one of the therapy delivery elements closer to or further from the targeted tissue.

**[0016]** According to another aspect, there is provided an implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising:

- (a) a ventral side having at least one therapy delivery element;
- (b) at least one means attached to the ventral side of the lead capable of movement; and
- (c) a membrane covering the means capable of movement, whereby movement of the means capable of movement results in lead expansion and positioning of at least one of the therapy delivery elements closer to or further from the targeted tissue.

**[0017]** According to another aspect, there is provided an implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising:

- (a) a ventral side having at least one therapy delivery elements;
- (b) at least one gear mechanism attached to the lead capable of rotating; and
- (e) at least one arm coupled to the gear; whereby rotation of at least one arm results in lead expansion and positioning of at least one of the therapy delivery elements closer to or further from the targeted tissue.

**[0018]** In other embodiments of the present invention, one or more therapy delivery elements may be placed within the cranial or vertebral bone of the patient so as to maintain the therapy delivery elements in a fixed position relative to the targeted neural tissue. The therapy delivery elements may thereafter be adjusted with a position control mechanism and/or a position controller to improve the desired treatment therapy.

**[0019]** By using the foregoing techniques, therapy delivery elements may be positioned to provide treatment therapy such as electrical stimulation and/or drug infusion to a precise target. Additionally, the present

invention accounts for the problems associated with lead migration, histological changes, neural plasticity or disease progression.

[0020] Optionally, the present invention may incorporate a closed-loop system which may automatically adjust (1) the positioning of the therapy delivery elements in response to a sensed condition of the body such as a response to the treatment therapy; and/or (2) the treatment therapy parameters in response to a sensed symptom or an important related symptom indicative of the extent of the disorder being treated.

[0021] Examples of the more important features of this invention have been broadly outlined above so that the detailed description that follows may be better understood and so that contributions which this invention provides to the art may be better appreciated.

[0022] These and other advantages and features of the invention will become apparent upon reading the following detailed description, which is given by way of example only, and referring to the accompanying drawings in which like numbers refer to like parts throughout and in which:

Figure 1 depicts a neurostimulation device in accordance with an embodiment of the present invention;

Figure 2 is a cross-sectional view of spinal cord at spinal bone level T-6 having an implanted lead in accordance with a preferred embodiment of the present invention;

Figure 3 illustrates a position controller having metal bellows;

Figure 4 illustrates a position controller having a piston;

Figures 5A-D disclose embodiments of the present invention where electrodes are anchored within vertebral bones of the spinal cord;

Figure 6 discloses another embodiment of the present invention having a collar screwed into vertebral bone;

Figure 7 discloses another embodiment of the present invention having a collar with an "O" ring to hold an electrode housing in position by pressure;

Figures 8 and 9 disclose other embodiments of the present invention where a plurality of electrodes are anchored through vertebral bones of the spinal cord;

Figure 10 discloses another embodiment of the present invention where a balloon is implemented on a dorsal side of a paddle lead;

Figure 11 illustrates an alternative technique for adding or removing fluid to a balloon;

Figures 12A-B depict other embodiments wherein a plurality of balloons are implemented to allow more selective adjustment of the electrodes relative to the spinal cord;

Figures 13A-B illustrate another embodiment wherein the balloon includes a rigid or semi-rigid

dorsal component;

Figures 14A-B illustrate yet another embodiment wherein the balloon includes a rigid or semi-rigid dorsal component having a hinge;

Figure 15 depicts another embodiment of a reservoir system for adjusting fluid amounts in a lead;

Figure 16 depicts yet another embodiment of a reservoir system for adjusting fluid amounts in a lead;

Figures 17A-E disclose other embodiments whereby a portion of the lead body thickness is adjusted using gliders;

Figures 18A-C disclose yet other embodiments whereby a portion of the lead body thickness is adjusted using movable wires;

Figure 19 discloses yet another embodiment whereby a portion of the lead body thickness is adjusted using a piston and a spring;

Figure 20 discloses yet another embodiment whereby a portion of the lead body thickness is adjusted using a gear mechanism;

Figures 21A-C disclose various embodiments of the present invention utilizing a single or dual gear mechanism;

Figures 22 and 23 illustrate embodiments of the present invention where more than one of the elements of the above figures are implemented;

Figure 24 illustrates yet another embodiment of a lead having two spans extending laterally from its body;

Figure 25 illustrates yet another embodiment of a lead having two spans that are adjustable by use of guide struts;

Figure 26 discloses an embodiment of a paddle lead having movable lateral spans;

Figures 27A-B disclose yet another embodiment of a paddle lead capable of extending electrodes laterally;

Figure 28 is a schematic block diagram of a sensor and an analog to digital converter circuit used in a preferred embodiment of the invention;

Figure 29 is a flow chart illustrating a preferred form of a microprocessor program for utilizing the sensor to control the treatment therapy provided to the neural tissue;

Figure 30 is a schematic block diagram of a microprocessor and related circuitry used in a preferred embodiment of the invention;

Figures 31-35 are flow charts illustrating a preferred form of a microprocessor program for generating stimulation pulses to be administered to neural tissue;

Figures 36A-D illustrate other embodiments of a lead being implanted within a vertebral bone of a patient;

Figures 37A-B illustrate an embodiment of an extendable lead for implant within a brain; and

Figures 38A-C illustrate an embodiment of the present invention wherein a plurality of MCEs are

implanted within the skull of a patient.

**[0023]** Figure 1 depicts a neurostimulation therapy delivery device 14 in accordance with an embodiment of the present invention. Therapy delivery device 14 made in accordance with the preferred embodiment is preferably implanted below the skin of a patient or, alternatively, may be an external device. Therapy delivery device 14 may be implanted as shown in Figure 1, in the abdomen or any other portion of the body 10. One or more leads 23 are positioned to stimulate a specific site in a spinal cord 12. Therapy delivery device 14 may take the form of a modified signal generator Model 7424 manufactured by Medtronic, Inc. under the trademark Itriel II®. Lead 23 may take the form of any of the leads sold with the Model 7424, for stimulating a spinal cord, and is coupled to therapy delivery device 14 by one or more conventional conductors 16 and 18. Lead 23 may include a paddle lead, a lead having one or more therapy delivery devices such as stimulation electrodes and/or catheters, or a combination catheter/lead capable of providing electrical stimulation and drug delivery. Lead 23 may also have recording electrodes. Exemplary embodiments of lead 23 incorporating the principles of the present invention are shown in the figures of the present application and discussed herein.

**[0024]** As shown in Figure 1, the distal end of lead 23 terminates in one or more therapy delivery elements such as stimulation electrodes generally implanted into or near a selected portion of the spinal cord by conventional surgical techniques. The location of the electrodes is determined by the type of treatment that is desired. Any number of electrodes may be used for various applications. Each of the electrodes are preferably individually connected to therapy delivery device 14 through lead 23 and conductors 16 and 18. Lead 23 is surgically implanted either by a laminotomy or by a percutaneous needle.

**[0025]** Therapy delivery device or signal generator 14 may be programmed to provide a predetermined stimulation dosage in terms of pulse amplitude, pulse width, pulse frequency, or duty cycle. As preferred, a programmer 20 may be utilized to provide stimulation parameters to therapy delivery device 14 via telemetry. Programmer is coupled to an antenna 24 via conductor 22.

**[0026]** The system may optionally include one or more sensors to provide closed-loop feedback control of the treatment therapy and/or electrode positioning. One or more sensors are attached to or implanted into a portion of a patient's body suitable for detecting a physical and/or chemical symptom or an important related symptom of the body. The feedback aspect of the present invention is discussed in further detail herein.

**[0027]** Although the invention will be described herein with reference to spinal cord stimulation (SCS) procedures, Cortical Surface Stimulation, and or Deep Brain Stimulation (DBS) it will be recognized that the

invention finds utility in applications other than SCS procedures, including other applications such as Peripheral Nerve or Ganglia Stimulation, Intra-Spinal Stimulation, Sacral Root Stimulation, or Intraventricular Cerebral Stimulation. In addition, the invention finds applicability to SCS procedures where the lead is placed in the intrathecal or subdural space. The present invention may also be utilized to provide stimulation of various muscles of the body such as the cardiac muscle. The invention also finds utility to drug therapy where electrical components are replaced with conduits and catheters for conducting drug material to the therapy site. In this case, especially, the lead may be placed in the intrathecal or subdural space.

**[0028]** Figure 2 is a cross-sectional view of spinal cord 12 at spinal bone level T-6 having an implanted lead 23A in accordance with a preferred embodiment of the present invention. Spinal cord 12 generally includes white matter 31, grey matter 33, and a surrounding dural sack 30. As shown, lead 23A is implanted in the epidural space outside of dural sack 30, but may alternatively be implanted in intrathecal spinal space or subcortically beneath dura 30. Lead 23A has a curved shape to match the shape of dura 30. The curvature may be matched to each spinal level or may be a general shape to approximately match all levels of spinal cord. Alternatively, lead 23A may be flat such that it "grips" the vertebral bone on its dorsal edges and is less prone to migration or rotation. Lead 23A has a dorsal side 125 away from spinal cord 12 and a ventral side 120 facing spinal cord 12.

**[0029]** Figures 2-4 show the average width, height and spacing of tissue components at vertebral bone level T6. The dashed lines in these figures indicate distances of one standard deviation from the mean. See J. Holsheimer et al., "MR Assessment of the Normal Position of the Spinal Cord in the Spinal Canal," Am. J. Neuroradiology, Vol. 15, pp. 951-959 (1994).

**[0030]** Referring still to Figure 2, lead 23A has two lateral electrode contacts 31 and 32 at opposite ends of lead 23A and a central electrode contact 33 in the central portion of lead 23A. Lateral and central electrodes 31-33 may be anodes, cathodes or nonactive. Alternatively, any one or more of lateral and central electrodes 31-33 may be recording electrodes or drug delivery ports. Lead 23A is preferably able to control the dorsal cerebral spinal fluid (CSF) width, even though it is placed outside of dura. In accordance with the present invention, lead 23A includes a position control mechanism capable of adjusting the position of one or more of the lateral or central electrodes 31-33. As shown, central electrode 33 is at a maximal distance dorsally from spinal cord 12. A position control mechanism may adjust the distance between central electrode 33 and the spinal cord 12. In the embodiment of Figure 2, the position control mechanism is in the form of a cavity 34 within lead 23A which is able to expand and fill with fluid (controlled by a pump (not shown)) or other matter in

the epidural space to reduce the separation between central electrode 33 and spinal cord 12. A pump (not shown) may be powered by signal generator 14 that also provides the stimulation energy for the electrodes at lateral and central electrodes 31-33 and a signal for controlling the position control mechanism. Alternatively, position control mechanism may be adjusted using external means and power such as a magnetic signal, a percutaneous needle or bulb on another component that can be pushed. Advantageously, central electrode 33 may be positioned such that the targeted neural tissue is stimulated with optimal efficacy and minimal side effects.

**[0031]** As shown in Figures 3 and 4, the position control mechanism may take any number of embodiments for allowing movement of the electrodes and holding the electrodes in position. Figure 3 illustrates a position control mechanism having metal bellows 35 and Figure 4 illustrates a position control mechanism having a piston 36. The bellows 35 of Figure 3 may alternatively be a threaded rod. A spring may be added to return the electrode to a less extended position.

**[0032]** Further, the position control mechanism may control all or a selective group of electrodes. For example, one position control mechanism may control a longitudinal or transverse row of electrodes. Alternatively, each electrode to be adjusted may have its own individual position control mechanism.

**[0033]** The position control mechanism of the above embodiments is preferably controlled by a position controller which is discussed in further detail herein. The position control mechanism is preferably adjustable such that it does not unduly depress neural tissue or hinder blood flow. Sensing feedback may be utilized, for example by a mechanical measure within a lead or an ultrasound or other sensor to give information about the distance. Sensing feedback may also be utilized to automatically adjust the positioning of the electrodes to provide optimum treatment therapy. Sensing feedback is discussed in further detail herein.

**[0034]** Figures 5-9 disclose another group of embodiments of the present invention where electrodes are anchored to vertebral bones of the spinal cord. Alternatively, the electrodes may be implanted in the cortical bone of the skull. Electrodes may be positioned by drilling one or more holes at preselected locations in the bone. Leads having one or more electrodes may then be passed through the holes and positioned inside the vertebral canal/skull at optimal locations or distances from the target neural tissue. Electrodes may then be selectively adjusted in position after the implant. The depth of the electrodes may then be adjusted to provide the optimal stimulation therapy.

**[0035]** As shown in Figure 5A, an electrode 40 at the end of a threaded housing 43 is provided by drilling housing 43 into bone 42 surrounding spinal cord 12. For dorsal column stimulation, bone 42 is preferably the dorsal aspect of vertebral bone. The lead 23B is coupled to

electrode 40 and extends out through a top portion 41 of threaded housing 43. Figures 5B-D illustrate exemplary embodiments of the top portion of housing 41 to allow for engagement of various turning devices. Figure 5B depicts a cavity 45 to provide engagement of a screwdriver-like device to turn housing 43 to adjust position of electrode 40 relative to spinal cord 12. Figure 5C depicts a similar device but providing engagement of a slotted screwdriver-like device. Figure 5D depicts a hexagonal cavity 47 for engagement of a hexagonal wrench-like device or percutaneous needle. Housing 43 preferably is threaded with a high pitch so that a relatively small turn provides relatively larger positioning of electrode 40 relative to the spinal cord 12. This minimizes the problem of lead 23B wrapping around housing 43.

**[0036]** Figure 6 discloses another embodiment of the present invention having a collar 50 screwed into bone 42. An inner housing 52 similar to the housing 43 of Figure 5 may be used to move electrode 40 relative to collar 50. This embodiment allows adjustment of electrode 40 at times after the system has been implanted and is less affected by growth of tissue over housing 52 and collar 51 to limit subsequent turning of housing 52 relative to collar 51. Figure 7 discloses another embodiment where collar 51 has an "O" ring 54 to hold housing 53 in position by pressure. Other means to lock housing 53 in position are also possible.

**[0037]** As shown in Figures 8 and 9, a plurality of electrodes may be provided that can be selectively or collectively adjusted relative to spinal cord 12. These electrodes may also be provided in a three-dimensional configuration along spinal cord 12. Further, though electrodes may be positioned closer to spinal cord 12, they preferably do not break the dural sack 30 to avoid leakage of CSF. Figure 9 shows a ball and socket 905 or other swivel mechanism to allow turning of the housing but not the lead. Advantageously, placement of the lead through the vertebral bone avoids the problem of lead migration.

**[0038]** Alternatively, the lead may be implanted into the bone, as opposed to implant all the way through the bone, as illustrated in Figures 36A-D. For example, Figure 36A depicts a lead 5 implanted into the bony aspects of the vertebral body. The lumbar spine is shown with the lead inserted into the pedicle 2 of the vertebral body 1 to stimulate nerve roots, particularly as the nerve roots 3 exit the spinal foramen 4. The lead 5 is implanted by drilling a hole through the pedicle 2 (from the posterior) and into the vertebral body. The lead 5 may then be inserted into the hole and fed to the end. Once in position, the lead 5 may be anchored at the posterior bone entrance site using, for example, a burr cap. By keeping the lead hole medial and centered, the nerve roots can be stimulated. The specific target nerve site may be selected by varying the placement of the lead 5 relative to the vertebral bone. Figure 36B shows an isometric drawing of pedicular placement for stimula-

tion of the nerve root as it exits the spinal foramen 4. Lead 5 is inserted into the inferior portion of the vertebral pedicle 2 of the vertebral segment to enable stimulation of the dorsal root ganglion 6. By way of another example, in Figure 36C, a lead 5 placed in the superior lateral portion of the vertebral bone will enable stimulation of the spinal nerve 7 of the segment superior. Advantageously, lead 5 may be placed so as to target desired neural tissue and avoid other tissue. In addition, lead 5 is anchored within the vertebral bone, thereby avoiding the risk of lead migration and avoiding compression of nerve tissue common in known techniques.

[0039] In addition, lead 5 may be implanted in any other bone areas that are proximal to targeted neural tissue. An example of placement to target other neural tissue is illustrated in Figure 36C. This Figure illustrates placement for stimulation of the ganglia (8) of the sympathetic trunk. The hole for lead 5 is angled more lateral and made deeper up to the wall of the vertebral body 1. Figure 36D is an isometric view of the same lead placement shown in Figure 36C. The hole in the vertebrae begins at the posterior and is extended down the pedicle 2, into the vertebral body 1, toward the ganglion 8, but not through the wall of the vertebral body. This method allows stimulation of deep tissues without disrupting soft tissue. Again the lead could be anchored in the posterior bone by a burr hole cap or other means. Lead 5 of Figures 36A-D may be adjustable similar to those of Figures 5-9.

[0040] The advantages of fixing a lead to a vertebral bone may also be implemented in Cortical Brain Stimulation applications. Figure 38A discloses another embodiment where one or more motor cortex electrodes (MCE) 308 are implanted into the skull of a patient for stimulation and/or recording of the cortex via contact with the dura. As shown in Figure 38B, MCE 308 may be screwed using a burr hole ring 309 and screw 310 within the skull 311 of a patient using known techniques. Advantageously, the present embodiment enables several MCEs 308 to be placed to allow flexibility in choosing the best stimulation. A MCE targeting grid (Figure 38C) could be constructed of a material such as, for example, CuSO<sub>4</sub>, so that the hole locations are visible under magnetic resonance imaging (MRI). Placement of the MCE 308 within the skull 311 allows for more accurate placement of the MCEs 308 and avoids the problem of lead migration. In addition, screw 310, referring to Figure 38B, can be advanced or retracted to ensure an optimal contact between the electrode 308 and dura 314 to maximize stimulation effect while minimizing mechanical deformation of dura and cortex. Further, less invasive surgical procedure is required, thereby minimizing the risk of damage to the dura 314. Such a configuration of MCEs 308 may be used for cortex stimulation for any number of disorders, including but not limited to, pain, epilepsy, anxiety/physiological disorders, and movement disorders.

[0041] In addition to minimizing lead migration, the

present invention also allows the lead to be positioned to be optimally closer to the desired treatment area. The embodiments discussed herein illustrate the various techniques that may be used to non-invasively position and re-position therapy delivery elements after they have been surgically implanted. Positioning of the treatment delivery elements may be laterally in any direction or toward or away from the desired treatment site. Figure 10 discloses an embodiment of the present invention where a balloon-like structure 60 is implemented on a dorsal side of a paddle lead 62. The balloon may also be positioned on a lateral side of paddle lead 62. Paddle lead 62 may have one or more electrodes 64. Lead 62 may be positioned closer to spinal cord 12 by filling of balloon 60 with a fluid. In the event that it is desired that lead 62 be moved away from spinal cord 12, fluid may be removed from 60. Figures 12A-B depict other embodiments wherein a plurality of balloons are implemented to allow more selective adjustment of the electrodes 64 relative to the spinal cord 12. These or other balloons may also be positioned on the sides of the lead so that the lead may be positioned from right to left. Figures 13A-B illustrate another embodiment wherein balloon 90 includes a rigid or semi-rigid dorsal component 92. Figures 14A-B illustrate yet another embodiment wherein balloon 94 includes a rigid or semi-rigid dorsal component 98 having a hinge 96 to allow component to form to the shape of the dorsal aspect of the patient's vertebral canal when balloon 94 is filled with fluid.

[0042] The amount of fluid in the balloon of Figures 12A-B, 13A-B and 14A-B may be controlled by a device similar to the position mechanism of Figure 2. These balloons may be made of an elastic or inelastic material. Figure 11 illustrates an alternative technique for adding or removing fluid to balloon 60. A septum 70 is provided just underneath the skin 72 of the patient. A noncoring needle 74 may be utilized to deliver or remove additional fluid to a reservoir 76 via septum 70. The delivery or removal of fluid may then be controlled to any one of the balloons via tube 78 as needed. Figure 15 depicts another embodiment wherein a separate reservoir and septum pair is provided for each of two balloons. In the case of three balloons, three reservoir/septum pairs may be provided. Figure 16 discloses yet another embodiment wherein a single septum 80 is provided but reservoirs 82 and 84 may transfer fluid between each other. Each reservoir has an associated bulb or depression mechanism 86A-B that can be accessed externally by pressing on the skin 72 of the patient. Each depression mechanism includes a spring 87 and ball 88 assembly. For example, by depressing mechanism 86B, fluid may be delivered from area 79B of reservoir 84 to reservoir 82 via tube 89. Also, when bulb 86A is depressed, fluid in area 79A is delivered from reservoir 82 to reservoir 84. Also, a separate reservoir may be utilized to add or remove fluid from reservoirs 82 and 84. Such systems are known in the art for an inflatable urinary sphincter and an inflatable penile erector. The sys-

tem may allow the patient to make these adjustments as needed.

**[0043]** Figures 17A-E disclose other embodiments whereby the electrodes are adjusted using gliders GL1 and GL2. As shown in Figures 17A-B, gliders GL1 and GL2 are constrained to move along a groove 115 transverse to ventral component 120 of lead as shown in Figure 17C. One or more pulley systems with wires may be utilized to move gliders GL1 and GL2 individually or collectively. Referring back to Figures 17A-B, gliders GL1 and GL2 are attached to ends of rigid arms L1 and L4 respectively. The opposite ends of arms L1 and L4 are attached to joints J1 and J4 respectively which are fixed relative to a semi-rigid or flexible dorsal component 110. Joints J1 and J4 are also connected to ends of rigid arms L2 and L3 respectively. Opposite ends of arms L2 and L3 are attached to joints S2 and S1 respectively which are fixed relative to ventral component 120 of the lead. The entire assembly may be encased within a membrane-like housing 130 to prevent connective tissue in-growth. Ventral component 120 may be positioned closer to spinal cord 12 by moving gliders GL1 and GL2 relative to groove 115. As shown in Figure 17B, ventral component 120 may be closest to spinal cord when gliders GL1 and GL2 are positioned under the joints J1 and J4. A glider may also be positioned to move parallel to spinal cord 12 along the lead. As shown in Figure 17D-E, any number of glider geometries may be utilized to adjust to adjust the position of ventral component 120.

**[0044]** Figures 18A-C disclose yet other embodiments whereby the electrodes are adjusted using movable, flexing wires. As shown in Figure 18A, ventral component 120 of a lead is positioned relative a semi-rigid dorsal component 125. Wires 137 are positioned at opposite sides of the assembly. As shown in Figure 18B, wire 137 is implemented within a sheath 131 whose end is fixed to ventral component 120. The distal end of wire 137 is anchored at point P1 and is also fixed relative to ventral component 120 of the lead. Wire 137 may be pushed or pulled along sheath 131 causing it to bend or straighten along its body 138. As wire 137 is pushed toward point P1, it bends causing the body 138 to exert pressure against dorsal component 125 and end P1 to exert pressure against ventral component 120. Wire 137 thus causes a portion of ventral component 120 to move away from dorsal component 125 thereby causing a portion of the lead to expand and position electrodes E1 on that portion to move closer to the spinal cord 12. When wire 137 is pulled back away from point P1, wire 137 reduces its pressure exerted on dorsal and ventral components 120 and 125, thereby allowing a portion of the lead to reduce its thickness and electrodes E1 on that portion to move away from spinal cord 12. As shown in Figure 18C, a plurality of wire assemblies may be incorporated to adjust the position of lead 120 relative to the spinal cord 12 along various points.

**[0045]** Figure 19 discloses yet another embodiment whereby the electrodes are adjusted using a piston C1 and a spring S1. Piston C1 may be moved to push or pull ventral component 120 relative to semi-rigid dorsal component 125. Spring S1 has a preset tension to return ventral component 120 to a default position once the pressure exerted by piston C1 is removed. As in the previously discussed embodiments, more than one piston/spring assembly may be located laterally as well as along the length of the lead. Alternatively, bellows may be used in place of piston C1 and spring S1.

**[0046]** Figure 20 discloses yet another embodiment whereby the lead is adjusted using a gear mechanism. A gear 160 may be rotated about an axis but is held in a fixed position relative to either semi-rigid dorsal component 125 or ventral component 120. Slidable elements 165 have ramped surfaces with teeth that interact with gear 160. The upper element 165 is coupled to slide relative to semi-rigid dorsal component 125 and the lower slidable element is coupled to slide relative to ventral component 120. As gear rotates, slidable elements 165 are moved in opposite directions relative to each other. With a clockwise turn of gear 160, lower element 165 slides to the left and upper element slides to the right. The elements thereby push ventral component 120 away from semi-rigid dorsal component 125 and toward spinal cord 12. Two or more gears may be implemented to minimize asymmetry in lead thickness.

**[0047]** As shown in Figures 21A-C, a gear mechanism may be incorporated into any number of embodiments. Figure 21A discloses a toggle mechanism having one gear 170 attached to a component with an associated left or right wing 171. As gear 170 is rotated, wings 171 are rotated accordingly. As shown in Figure 21B, rotation of wings 171 counter-clockwise pushes up against semi-rigid dorsal component 125 causing that portion of lead to increase its thickness, thereby moving that portion of ventral component 120 toward spinal cord 12. Gear 170 may be controlled by slidable toothed elements 175. As shown in Figure 21C, there may be two gears (one is shown), each connected to a single-sided wing 171a or 171b to change the lateral lead thickness independently. Wings 171a-b may also have transverse extensions 173a-b (parallel to spinal cord 12) to push against dorsal component 125.

**[0048]** The lead may be configured in any number of ways using any combination of the above-detailed structures. For example, Figures 22 and 23 illustrate that two or more of the above-detailed techniques (such as wings, flexing wires and/or springs) may be combined to provide the desired control of lead thickness.

**[0049]** Figure 24 illustrates yet another embodiment of a lead according to a preferred embodiment of the present invention for use in SCS therapy. This design allows movement of electrodes toward or along spinal nerve roots within the spinal canal as they pass caudally and laterally toward their respective foraminae (exits from the vertebral bones). In accordance with known



techniques, a Tuohy needle 314 is utilized and positioned near the spinal cord. Lead body 318 is inserted through the lumen 316 of Tuohy needle 314 and positioned near the spinal cord 12. A proximal end (not shown) of lead body 318 is ultimately to be connected to a source device (not shown) which may be signal generator 14 of Figure 1, in the case of electrical stimulation, or a drug pump in the case of drug therapy. Lead 318 is provided with a distal tip 320 that may be compacted for insertion and unfolded after it has been positioned appropriately within the body. Distal tip 320 includes a central portion 322 and at least one span 324 depending therefrom. Span 324 is comprised of a flexible, insulative material, such as polyurethane or silicone rubber. The term "flexible" as used herein refers to both resilient and non-resilient materials. Central portion 322 may have a generally semi-circular cross-section as shown, or may be flat such as in the case of a paddle lead (exemplified in Figure 26). Affixed to a surface of spans 324 and to central portion 322 is a series of electrodes 326. In accordance with the invention, lead 320 may be configured into a compact insertion position for ease of insertion through lumen 316 of Tuohy needle 314.

**[0050]** Once in position near the implant site, lead tip 320 may be deployed out of Tuohy needle 314, as shown in Figure 24. In the embodiment of Figure 24, spans 324 are semirigid and tend to span out at a predetermined angle. To optimally position lead spans 324 along spinal nerve roots, lead 320 may be pulled back into the Tuohy needle 314. As it moves back, spans 324 will tend to move laterally as well as downward, along the path of a nerve root. Needle 314 may be replaced by a sheath component for adjustments after implant. In the embodiment of Figure 25, spans 324 may be rigid or flaccid and are coupled to a lever 330 capable of adjusting the lateral displacement of spans 324. Lever 330 extends from spans 324 to body struts 319. Struts 319 pass inside or along lead body 318 to controllers (not shown). As lever 330 is moved toward distal end of lead 320 by pushing on struts 319, spans 324 are displaced further in a lateral direction. Lever 330 may be coupled to a control mechanism such that spans 324 may be repositioned at future times to provide optimal treatment therapy. Figure 26, discloses another embodiment of a paddle lead 420 having spans 424 which can rotate to lateral positions. Figures 27A-B disclose yet another embodiment of a paddle lead 520 capable of extending electrodes laterally to track along spinal nerves. Such a mechanism may be similar to that of a car antenna-like device whereby a rigid or semi-rigid wire may extend laterally from lead 520. An internal stylet 521 may be utilized to adjust the length of the span 522. As shown in Figure 27A, when stylet 521 is inserted within the lead 520 and is closest to the lead tip, the span 522 is retracted and inside lead 520. As stylet 521 is pulled to the left, span 522 is directed out as shown in Figure 27B to direct electrodes 523 laterally away from lead 520.

This embodiment may be incorporated with the embodiments of Figures 24-26 and 27A-B to allow adjustment of the extent of the lateral displacement as well as the angle of the lateral displacement.

**[0051]** The above embodiments illustrate various techniques for allowing therapy delivery elements to be positioned during and/or after implant to effectively provide treatment therapy to the targeted area of the spinal cord or brain. Further, relief may be provided with a lower amplitude, and motor or other undesirable side effects may be minimized. As exemplified in the above embodiments, any number of techniques may be utilized.

**[0052]** The present invention may also be utilized within the brain to provide electrical stimulation as well as delivery of one or more drugs. The present invention may be implemented within a system as disclosed in U.S. Patent Application entitled "Techniques For Selective Activation Of Neurons In The Brain, Spinal Cord Parenchyma, and Peripheral Nerve," invented by Mark Rise and Mike Baudino. Treatment therapy may be provided to the brain to treat any number of diseases. Sometimes, the disease will progress to another part of the brain. The present invention may thereby be used to advance the electrodes to a different part of the brain. For example, electrodes and/or catheters may be implanted within the brain to treat tremor. Later, it may be desirable to address symptoms of akinesia or bradykinesia which were not clearly present when the treatment device was originally implanted. The present invention may thereby extend or shorten the leads to effect different areas of the brain tissue. Alternatively, leads may be adjusted to achieve optimal positioning.

**[0053]** For example Figure 37A depicts a lead 37 composed of concentric tubes 38, preferably metal such as platinum. These tubes may be coated with a polymer except for the distal end portions 39 that serve as the electrodes. The conductive wires 40 carrying energy to the electrodes are in the interior of the concentric tubes. Optionally, the most distal electrode end 41 may be a small recording microelectrode to help assist in the actual placement of the lead. As shown in Figure 37B, the lead 37 may be implanted within the brain under known techniques. A pusher 42 may be placed into the lead through the proximal portion to make the lead 37 stiff during the introduction phase and/or to provide a mechanism to push the concentric tubes 38 out and away from the outer tube or cannula 43. After implant, the outer cannula 43 may optionally be removed.

**[0054]** The present invention may be operated as an open-loop controlled system. In an open-loop system, the physician or patient may at any time manually or by the use of pumps or motorized elements adjust the positioning of the electrodes in situ and change stimulation parameters. However, this subsequent position adjustment would be independent of any intended changes in stimulation effect or side-effects the patient may be experiencing, and an iterative procedure may be

necessary.

[0055] Optionally, the present invention may incorporate a closed-loop control system which may automatically adjust (1) the positioning of the electrodes in response to a sensed condition of the body such as a response to the treatment therapy; and/or (2) the electrical stimulation parameters in response to a sensed symptom or an important related symptom indicative of the extent of the disorder being treated. Under a closed-loop feedback system to provide automatic adjustment of the positioning of the electrodes, a sensor 130A (Figure 28) that senses a condition of the body is preferably utilized. For example, sensor 130A may detect patient position to discern whether the patient is lying down or is in an erect position. Typically, spinal cord stimulation becomes strong when the patient lies down due to the spinal cord moving in a dorsal direction toward the lead. In such a situation, the position control mechanism may adjust electrodes to move away from spinal cord. Alternatively, one or more recording electrodes may be utilized to provide feedback.

[0056] More detailed description of sensor 130A, other examples of sensors and the feedback control techniques are disclosed in U.S. Patent No. 5,716,377 entitled "Method of Treating Movement Disorders By Brain Infusion," issued on February 10, 1998 and assigned to Medtronic, Inc.

[0057] Referring to Figure 28, the output of sensor 130A is coupled by a cable 132 comprising conductors 134 and 135 to the input of analog to digital converter 140A. Alternatively the output of the sensor 130A could communicate through a "body bus" communication system as described in U.S. Patent No. 5,113,859 (Funke), assigned to Medtronic. Alternatively, the output of an external feedback sensor 130A would communicate with signal generator 14 through a telemetry down-link. The output of the analog to digital converter 140A is connected to a microprocessor 200 via terminals EF2 BAR and EF3 BAR. The sensor signals may then be stored in a memory device such as a Random Access Memory (RAM) 102a. Such a configuration may be one similar to that shown in U.S. Patent No. 4,692,147 ("147 Patent") except that before converter 140A is connected to the terminals, the demodulator of the '147 patent (identified by 101) would be disconnected. Microprocessor 200 may then be coupled to a position controller 201.

[0058] For some types of sensors, microprocessor 200 and analog to digital converter 140A would not be necessary. The output from sensor 130A can be filtered by an appropriate electronic filter in order to provide a control signal for position controller. An example of such a filter is found in U.S. Patent No. 5,259,387 "Muscle Artifact Filter", issued to Victor de Pinto on November 9, 1993.

[0059] Closed-loop control of position controller can be achieved by a modified form of the ITREL II signal generator. Referring to Figure 30, the output of the ana-

log to digital converter 140A is connected to microprocessor 200 through a peripheral bus 202 including address, data and control lines. Microprocessor 200 processes the sensor data in different ways depending on the type of transducer in use. Microprocessor may adjust the position of the electrodes in response to the sensor signal information provided by sensor 130A. The type of control provided depends upon the type of position controller utilized and the mechanism utilized (discussed above) to position the electrodes. In the case where position controller relies on electrical energy to cause mechanical movement (e.g., pumps, motors and the like) or is purely electrical control, microprocessor 200 or a second microprocessor may serve as the position controller. In the case where position requires mechanical control, an appropriate controlling device is used. For example, in the embodiment of Figure 10-16 where position is controlled by filling a balloon with fluid, position controller may be incorporated within a reservoir system for holding the fluid outside the lead's balloon. Torque from percutaneous instruments that engages in a mechanical component may also be used.

[0060] The present invention may also incorporate a closed-loop feedback system to provide automatic adjustment of the electrical stimulation therapy. Such is system is disclosed in U.S. Patent No. 5,792,186 entitled "Method and Apparatus of Treating Neurodegenerative Disorders by Electrical Brain Stimulation," and assigned to Medtronic, Inc. The system may incorporate the same sensor 130A discussed above or one or more additional sensors 130 to provide feedback to provide enhanced results. Sensor 130 can be used with a closed loop feedback system in order to automatically determine the level of electrical stimulation necessary to provide the desired treatment. For example, to treat motion disorders that result in abnormal movement of an arm, sensor 130 may be a motion detector implanted in the arm. More detailed description of sensor 130, other examples of sensors and the feedback control techniques are disclosed in U.S. Patent No. 5,716,377 entitled "Method of Treating Movement Disorders By Brain Infusion," issued on February 10, 1998 and assigned to Medtronic, Inc. Other such sensors are also disclosed in U.S. Patent Nos. 5,683,422; 5,702,429; 5,713,923; 5,716,316; 5,792,186; 5,814,014; and 5,824,021.

[0061] Closed-loop electrical stimulation can be achieved by a modified form of the ITREL II<sup>®</sup> signal generator which is described in Figure 30. The output of the analog to digital converter 206 is connected to a microprocessor 200 through a peripheral bus 202 including address, data and control lines. Microprocessor 200 processes the sensor data in different ways depending on the type of transducer in use. When the signal on sensor 130 exceeds a level programmed by the clinician and stored in a memory 204, increasing amounts of stimulation will be applied through an output driver 224. For some types of sensors, a microproces-

sensor and analog to digital converter will not be necessary. The output from sensor 130 can be filtered by an appropriate electronic filter in order to provide a control signal for signal generator 14. An example of such a filter is found in U.S. Patent No. 5,259,387 "Muscle Artifact Filter", Issued to Victor de Pinto on November 9, 1993.

**[0062]** Still referring to Figure 30, the stimulus pulse frequency is controlled by programming a value to a programmable frequency generator 208 using bus 202. The programmable frequency generator 208 provides an interrupt signal to microprocessor 200 through an interrupt line 210 when each stimulus pulse is to be generated. The frequency generator 208 may be implemented by model CDP1878 sold by Harris Corporation. The amplitude for each stimulus pulse is programmed to a digital to analog converter 218 using bus 202. The analog output is conveyed through a conductor 220 to an output driver circuit 224 to control stimulus amplitude. Microprocessor 200 also programs a pulse width control module 214 using bus 202. The pulse width control 214 provides an enabling pulse of duration equal to the pulse width via a conductor. Pulses with the selected characteristics are then delivered from signal generator 14 to the lead to the target locations of spinal cord 12.

**[0063]** Microprocessor 200 executes an algorithm shown in Figures 31-5 to provide stimulation with closed loop feedback control. At the time the stimulation signal generator 14 or an alternative device having stimulation and/or infusion functions is implanted, the clinician programs certain key parameters into the memory of the implanted device via telemetry. These parameters may be updated subsequently as needed. Step 400 in Figure 31 indicates the process of first choosing whether the neural activity at the stimulation site is to be blocked or facilitated (step 400(1)) and whether the sensor location is one for which an increase in the neural activity at that location is equivalent to an increase in neural activity at the stimulation target or vice versa (step 400(2)). Next the clinician must program the range of values for pulse width (step 400(3)), amplitude (step 400(4)) and frequency (step 400(5)) which signal generator 14 may use to optimize the therapy. The clinician may also choose the order in which the parameter changes are made (step 400(6)). Alternatively, the clinician may elect to use default values.

**[0064]** The algorithm for selecting parameters is different depending on whether the clinician has chosen to block the neural activity at the stimulation target or facilitate the neural activity. Figures 31-35 detail the steps of the algorithm to make parameter changes.

**[0065]** The algorithm uses the clinician programmed indication of whether the neurons at the particular location of the stimulating electrode are to be facilitated or blocked in order to decide which path of the parameter selection algorithm to follow (step 420, Figure 32). If the neuronal activity is to be blocked, signal generator 14 first reads the feedback sensor 130 in step

421. If the sensor values indicate the activity in the neurons is too high (step 450), the algorithm in this embodiment first increases the frequency of stimulation in step 424 provided this increase does not exceed the preset maximum value set by the physician. Step 423 checks for this condition. If the frequency parameter is not at the maximum, the algorithm returns to step 421 through path 421A to monitor the feedback signal from sensor 130.

**[0066]** If the frequency parameter is at the maximum, the algorithm next increases the pulse width in step 426 (Figure 33), again with the restriction that this parameter has not exceeded the maximum value as checked for in step 451 through path 423A. Not having reached maximum pulse width, the algorithm returns to step 421 to monitor the feedback signal from sensor 130. Should the maximum pulse width have been reached, the algorithm next increases amplitude in a like manner as shown in steps 427 and 428. In the event that all parameters reach the maximum, a notification message is set in step 429 to be sent by telemetry to the clinician indicating that therapy delivery device 14 is unable to reduce neural activity to the desired level.

**[0067]** If, on the other hand, the stimulation electrode is placed in a location which the clinician would like to activate to alter the symptoms of the neurological disorder, the algorithm would follow a different sequence of events. In the preferred embodiment, the frequency parameter would be fixed at a value chosen by the clinician to facilitate neuronal activity in step 430 (Figure 34) through path 420A (Figure 32). In steps 431 and 432 the algorithm uses the values of the feedback sensor to determine if neuronal activity is being adequately controlled. In this case, inadequate control indicates that the neuronal activity of the stimulation target is too low. Neuronal activity is increased by first increasing stimulation amplitude (step 434) provided it doesn't exceed the programmed maximum value checked for in step 433. When maximum amplitude is reached, the algorithm increases pulse width to its maximum value in steps 435 and 436 (Figure 35). A lack of adequate alteration of the symptoms of the neurological disorder, even though maximum parameters are used, is indicated to the clinician in step 437. After steps 434, 436 and 437, the algorithm returns to step 431 through path 431A, and the feedback sensor again is read.

**[0068]** It is desirable to reduce parameter values to the minimum level needed to establish the appropriate level of neuronal activity in the spinal cord. Superimposed on the algorithm just described is an additional algorithm to readjust all the parameter levels downward as far as possible. In Figure 31, steps 410 through 415 constitute the method to do this. When parameters are changed, a timer is reset in step 415. If there is no need to change any stimulus parameters before the timer has counted out, then it may be possible due to changes in neuronal activity to reduce the parameter values and still maintain appropriate levels of neuronal activity in

the target neurons. At the end of the programmed time interval, signal generator 14 tries reducing a parameter in step 413 to determine if control is maintained. If it is, the various parameter values will be ratcheted down until such time as the sensor values again indicate a need to increase them. While the algorithms in Figures 31-35 follow the order of parameter selection indicated, other sequences may be programmed by the clinician.

[0069] The stimulation might be applied periodically during the period of stimulation/infusion either routinely or in response to sensor or patient generated demand. Alternatively, in the case of simultaneous stimulation and drug therapy, stimulation could be applied continuously with infusion occurring periodically. Patient activation of either infusion or stimulation may occur as a result of an increase in symptoms being experienced by the patient. Alternatively, the infusion of an agent to activate a neuronal population might be alternated with application of electrical stimulation of that same population.

[0070] Advantageously, the present invention may be used to selectively position stimulation electrodes optimally closer to the targeted neural tissue to more effectively deliver a desired treatment therapy. The present invention may also be implemented within a drug delivery system and/or may be implemented to provide treatment therapy to other parts of the body such as the brain, nerves, muscle tissue, or neural ganglia. Further, the various embodiments of the present invention may be implemented within a percutaneous lead or a paddle lead.

#### Claims

1. A system for providing treatment therapy to targeted tissue comprising in combination:

- (a) a therapy delivery device;
- (b) at least one therapy delivery element coupled to the therapy delivery device for providing treatment therapy to the targeted tissue; and
- (c) at least one position control mechanism coupled to at least one of the therapy delivery elements for adjusting, at any time after implanting the therapy delivery elements, the position of the therapy delivery element relative to the targeted tissue.

2. A system of claim 1, wherein the therapy delivery device is a signal generator and the therapy delivery element is an electrode.

3. A system of claim 1, wherein the therapy delivery device is a pump and the therapy delivery element is a catheter.

4. A system of any preceding claim, further comprising:

- (d) a first sensor for generating a first sensor signal related to a condition of a body; and
- (e) position controller for adjusting the position of at least one of the therapy delivery elements in response to the first sensor signal.

5. A system of claim 4, wherein the sensor senses the body's response to the treatment therapy.

6. A system of any preceding claim, further comprising:

- (d) a second sensor for generating a second sensor signal indicative a condition to be treated; and

- (e) control means for regulating the operation of the therapy delivery device in response to the second sensor signal.

7. A system of any preceding claim, wherein the therapy delivery elements are part of a paddle lead.

8. A system of claim 7, wherein the therapy delivery elements have at least one cavity for holding fluid, wherein a change in fluid within the lead would direct at least one of the therapy delivery elements of the lead toward or away from targeted tissue.

9. A system of claim 7, wherein the therapy delivery elements have at least one bellows, wherein expansion or compression of the bellows would direct at least one of the therapy delivery elements of the lead toward or away from targeted tissue.

10. A system of claim 7, wherein the therapy delivery elements have at least one piston, wherein expansion or compression of the piston would direct at least one of the therapy delivery elements of the lead toward or away from targeted tissue.

11. A system of claim 7, wherein the therapy delivery elements have at least one piston and at least one spring, wherein expansion or compression of the piston or spring would direct at least one of the therapy delivery elements of the lead toward or away from targeted tissue.

12. A system of any of claim 7 to 11, wherein the therapy delivery elements are part of a paddle lead having a dorsal side and further comprising:

- (d) at least one inflatable balloon-like member attached to a dorsal side or a lateral side of the paddle lead and capable of being filled with fluid, wherein the addition or removal of fluid from at least one of the balloon-like members would direct at least one of the therapy delivery elements of the lead relative targeted tissue.

13. A system of claim 12, wherein the balloon-like member has one or more areas of inelastic material.
14. A system of claim 12 or 13, wherein the dorsal component has a hinge coupling two relatively rigid members.
15. A system of claim 7, further comprising:
- (d) at least one glider means attached the paddle lead capable of positioning at least a portion of the paddle lead relative to the targeted tissue.
16. A system of claim 7, further comprising:
- (d) at least one bendable wire means attached to the paddle lead capable of positioning at least a portion of the paddle lead relative to the targeted tissue.
17. A system of claim 7, further comprising:
- (d) at least one gear mechanism attached to the paddle lead capable of positioning at least a portion of the paddle lead relative to the targeted tissue.
18. A system of any preceding claim, wherein the therapy delivery elements are part of an implantable lead and wherein the lead has:
- i.  
an elongate central portion; and
- ii.  
at least one extendable member having an end, the extendable member depending from the central portion and being adapted to assume a compact position, in which the end is disposed in close proximity to the central portion, and an extended position, in which the end is disposed at a location distal from the central portion, wherein the therapy delivery elements are positioned at least on the extendable member.
19. An implantable lead for providing therapy to a body comprising:
- (a) an elongate central portion;  
(b) at least one extendable member having an end, the extendable member depending from the central portion and being adapted to assume a compact position, in which the end is disposed in close proximity to the central portion, and an extended position, in which the extendable member is disposed removed from the central portion; and  
(c) at least one therapy delivery element disposed on the extendable member for delivering therapy to the body.
20. The implantable lead according to claim 19, wherein the extendable member is disposed at an angle laterally from the central portion.
21. The implantable lead according to claim 19, wherein the extendable member includes a lever to adjust the angle of the extendable member.
22. The implantable lead according to claim 19, wherein, in said extended position, the end of the extendable member is disposed at a location distal from the central portion.
23. The implantable lead according to claim 22, further comprising  
a lever coupled near the end of the extendable member and the central portion capable of selectively adjusting the direction of extension of the extendable member relative to the central portion.
24. The implantable lead according to any of claims 19 to 23, wherein the span incorporates a resilient material to urge the span toward the extended position.
25. The implantable lead according to any of claims 19 to 24, wherein the lead is a paddle lead.
26. The implantable lead according to any of claims 19 to 25, wherein the extendable member may be elongated outwardly from the central portion to position the therapy delivery element toward or away from targeted tissue.
27. A system for providing neurostimulation therapy to targeted tissue comprising in combination:
- (a) a signal generator;  
(b) at least one housing member implantable within a bone near the targeted tissue and adjustable relative to the bone; and  
(c) at least one electrode coupled to said signal generator and attached to a distal end of the housing member for providing electrical stimulation to the targeted tissue.
28. A system of claim 27, further comprising  
(d) a collar implantable within a bone near the neural tissue, and  
wherein the housing member is insertable

- within the collar and is adjustable relative to the collar.
29. An implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising: 5
- (a) a middle portion having at least one central therapy delivery element on a ventral side;
  - (b) at least two end portions, each end portion having at least one end therapy delivery element on the ventral side; and 10
  - (c) means capable of expanding the middle portion such that the central therapy delivery element is positioned away from a dorsal side of the lead. 15
30. The lead of claim 29, wherein said means capable of expanding the middle portion comprises a fluid reservoir portion along the middle portion capable of receiving fluid. 20
31. The lead of claim 29, wherein said means capable of expanding the middle portion comprises 25
- a piston coupling the front side and a back side of the lead.
32. The lead of claim 29, wherein said means capable of expanding the middle portion comprises 30
- at least one bellows coupling the front side and a back side of the lead.
33. An implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising: 35
- (a) a ventral side having at least one therapy delivery element;
  - (b) a dorsal side opposite the ventral side; 40
  - (c) at least one balloon-like member attached to the back side of the lead, the balloon-like member capable of expanding by receiving a fluid, 45
  - whereby expansion of the balloon-like member resulting in positioning at least one of the therapy delivery elements closer to or further from the targeted tissue. 50
34. An implantable paddle-like lead of claim 33 wherein the balloon-like member has a relatively rigid component along a dorsal side of the member.
35. An implantable paddle-like lead of claim 34 wherein the relatively rigid component has a hinge coupling two relatively rigid members. 55
36. An implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising: 5
- (a) a ventral side having at least one therapy delivery element;
  - (b) at least one means attached to the ventral side of the lead capable of movement; and
  - (c) a membrane covering the means capable of movement, 10
  - whereby movement of the means capable of movement results in lead expansion and positioning of at least one of the therapy delivery elements closer to or further from the targeted tissue. 15
37. The lead of claim 36, wherein said means capable of movement comprises a glider mechanism.
38. The lead of claim 36, wherein said means capable of movement comprises 20
- at least one flexible wire means, whereby flexing of the flexible wire means results in said lead expansion and positioning of at least one of the therapy delivery elements closer to or further from the targeted tissue. 25
39. An implantable paddle-like lead for providing treatment therapy to targeted tissue of a body comprising: 30
- (a) a ventral side having at least one therapy delivery elements;
  - (b) at least one gear mechanism attached to the lead capable of rotating; and
  - (e) at least one arm coupled to the gear; 35
  - whereby rotation of at least one arm results in lead expansion and positioning of at least one of the therapy delivery elements closer to or further from the targeted tissue. 40

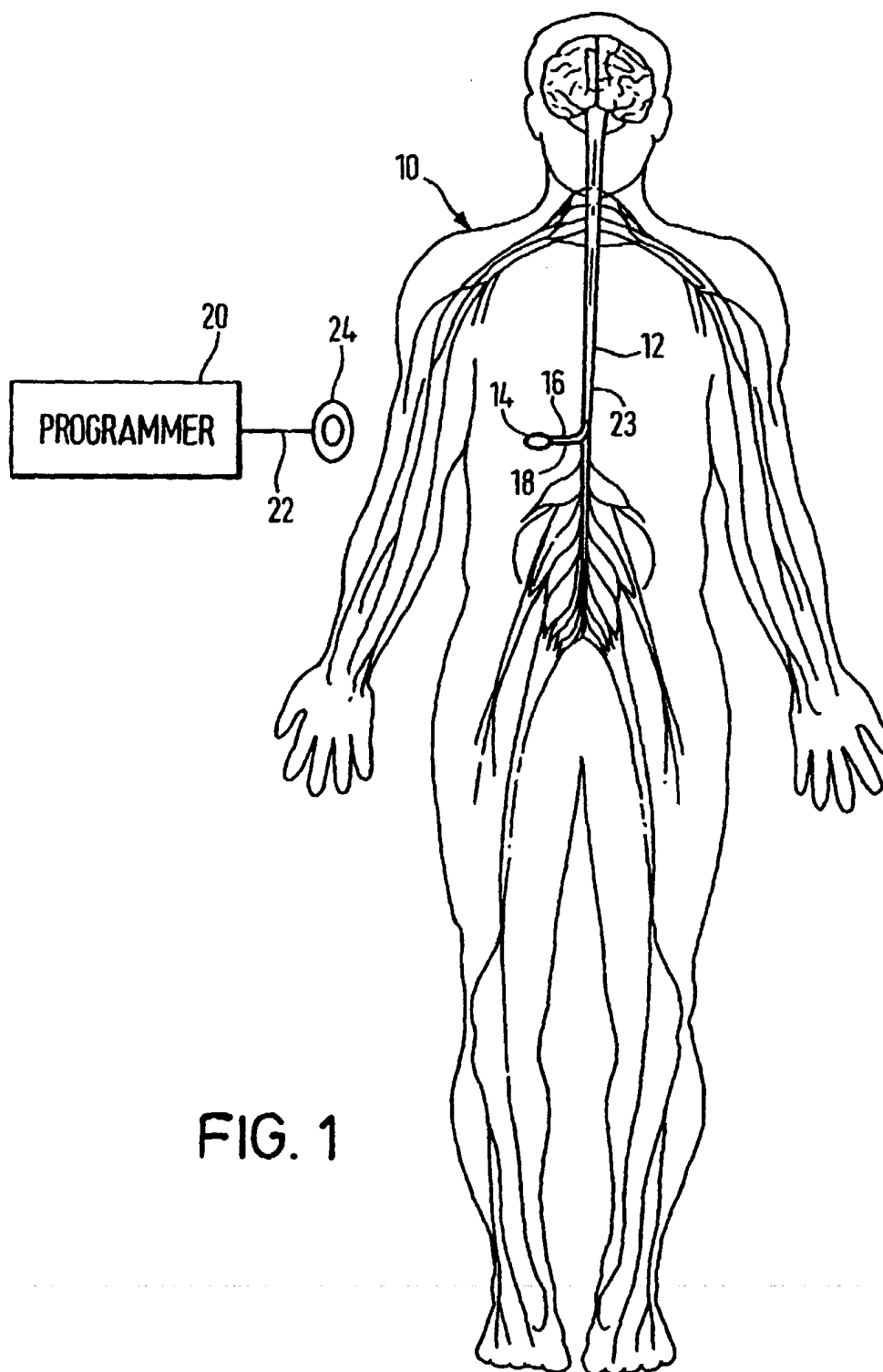


FIG. 1

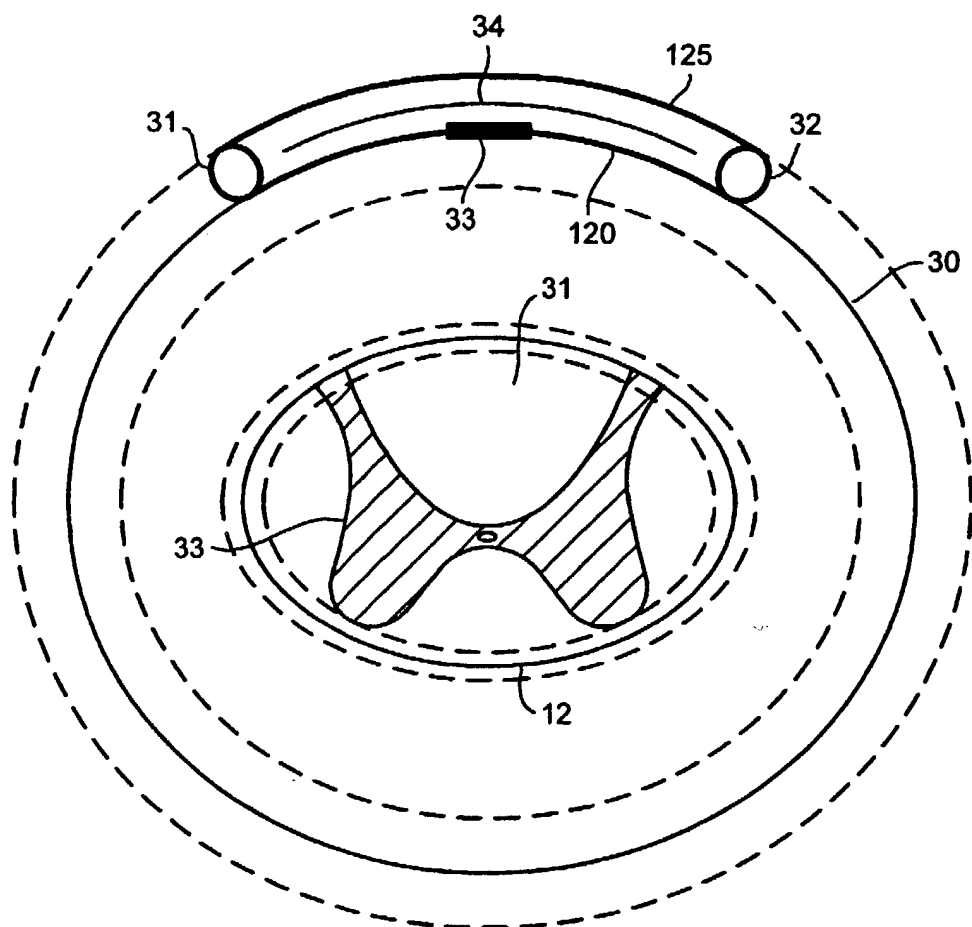


FIG. 2



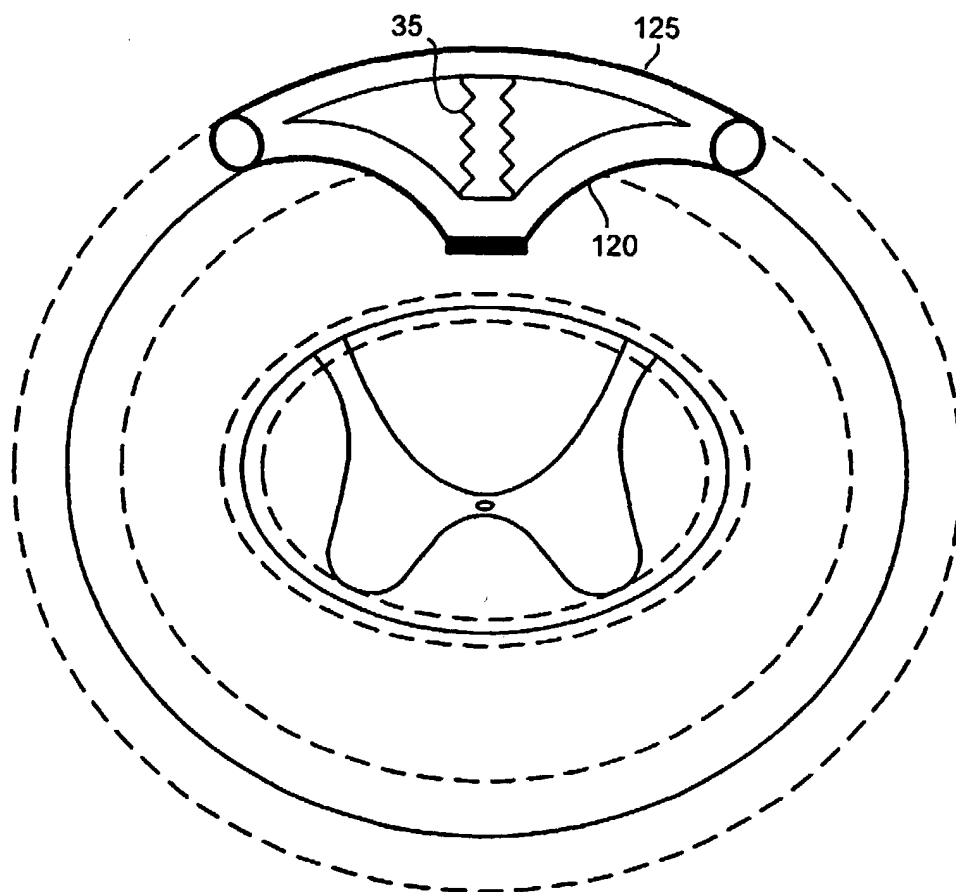


FIG. 3

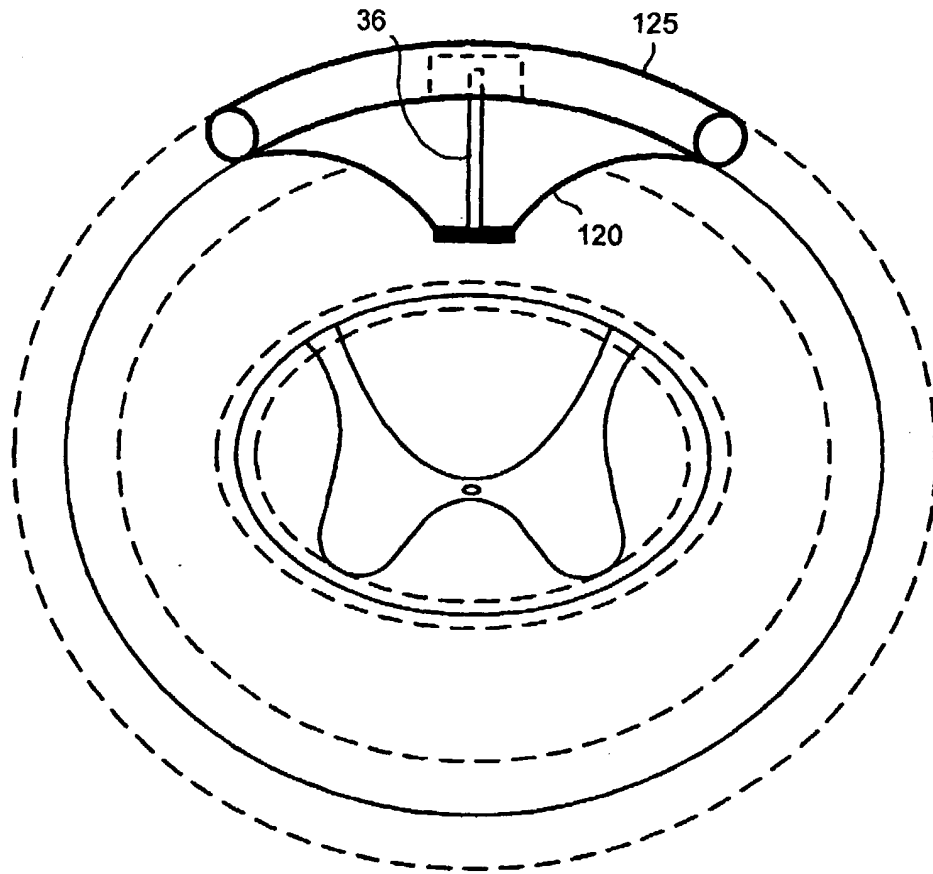


FIG. 4

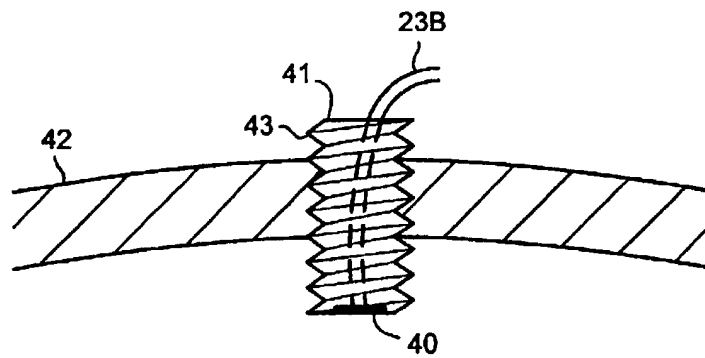


FIG. 5A

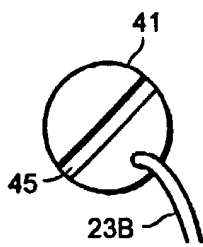


FIG. 5B

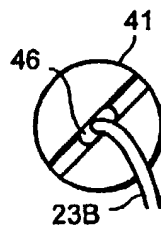


FIG. 5C

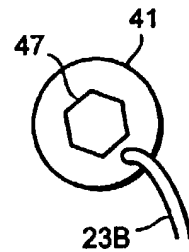


FIG. 5D

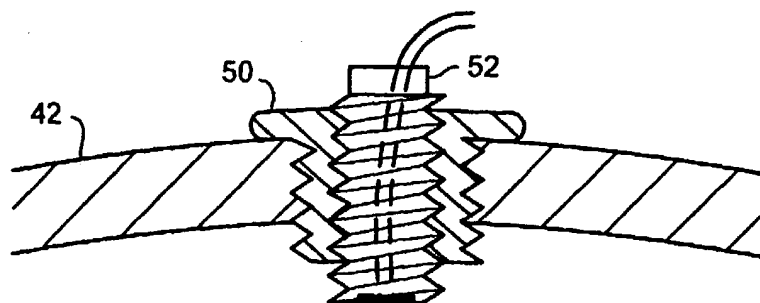


FIG. 6

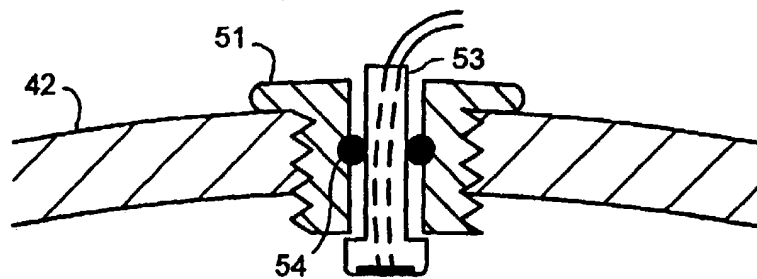


FIG. 7

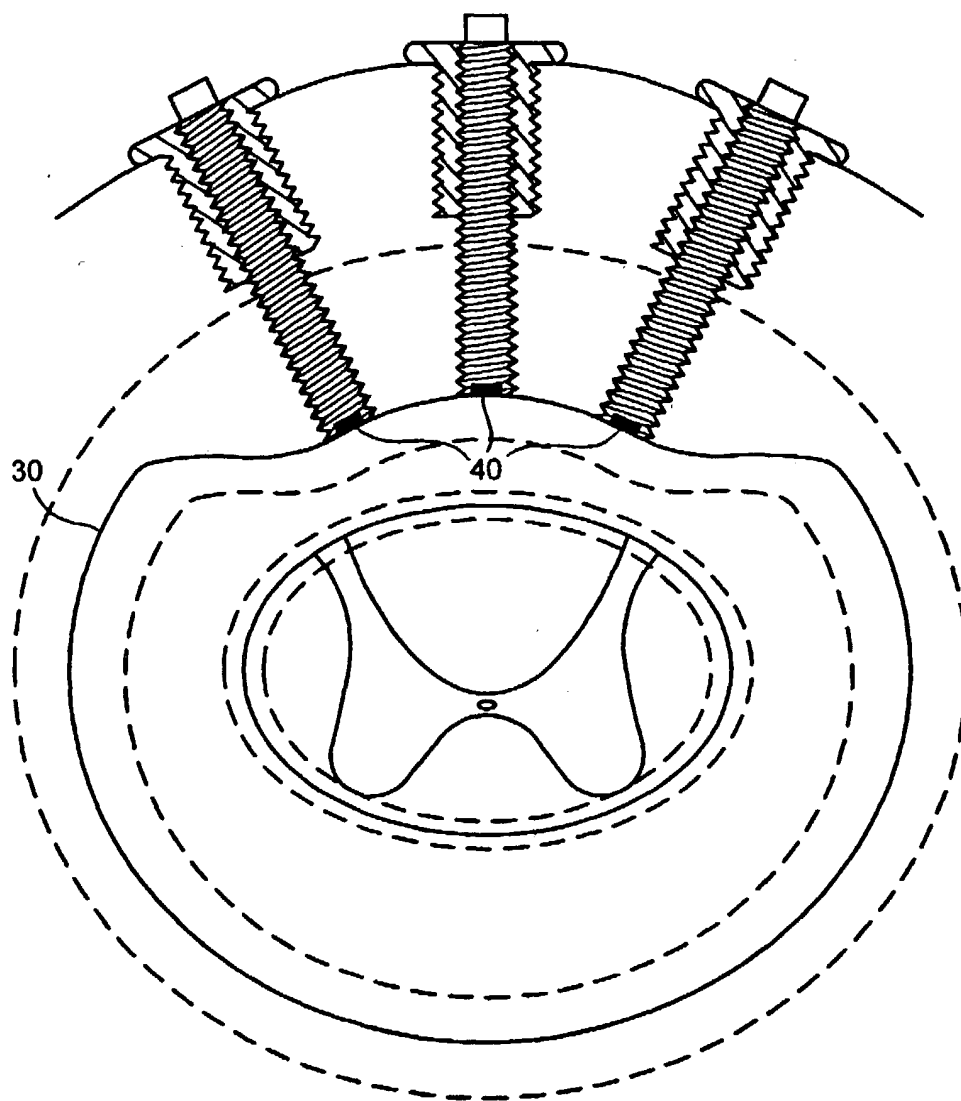


FIG. 8

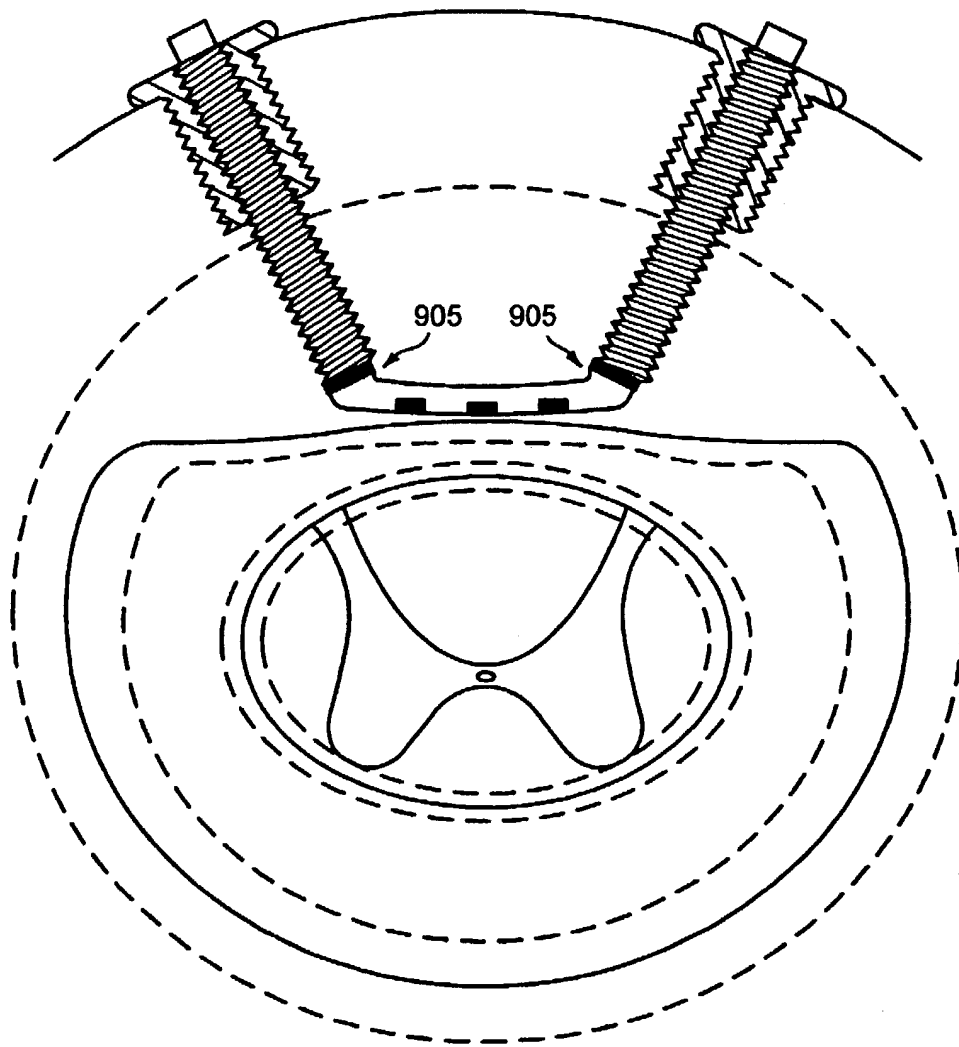


FIG. 9

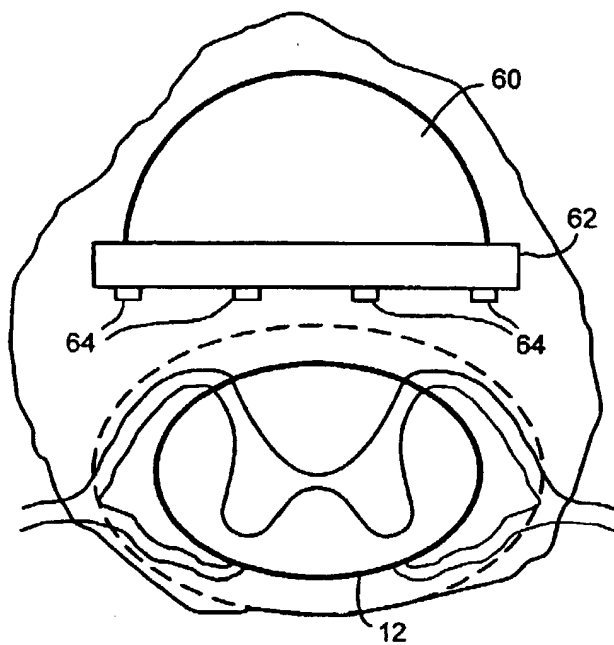


FIG. 10

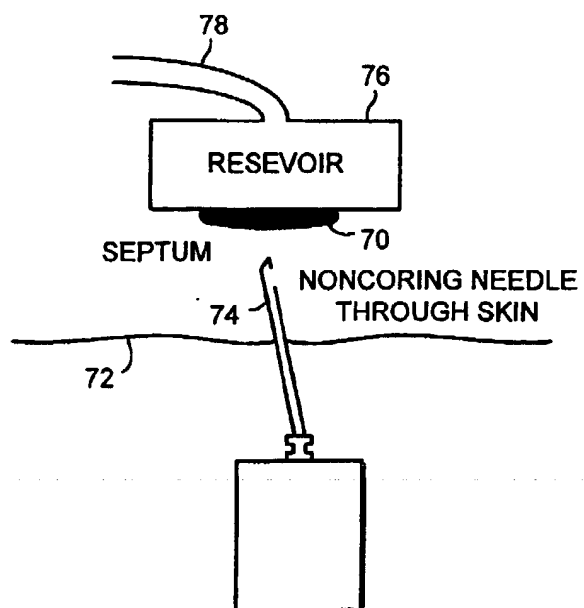


FIG. 11

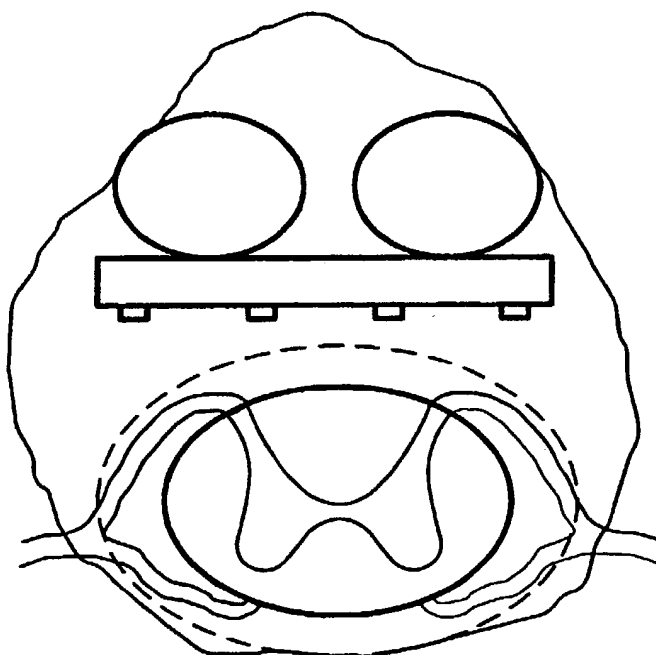


FIG. 12A

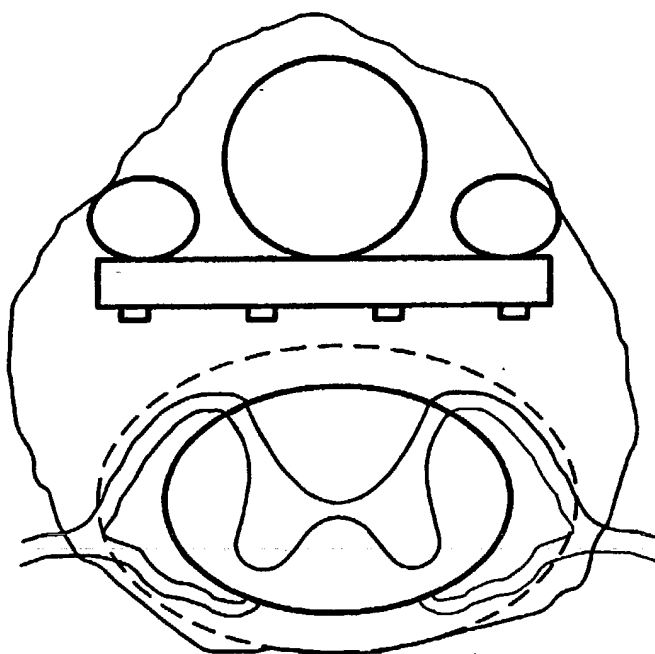


FIG. 12B



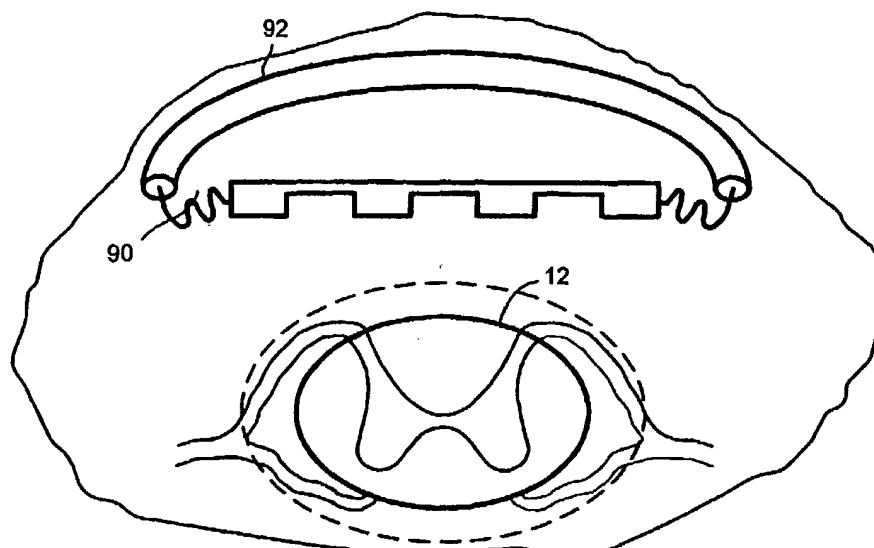


FIG. 13A

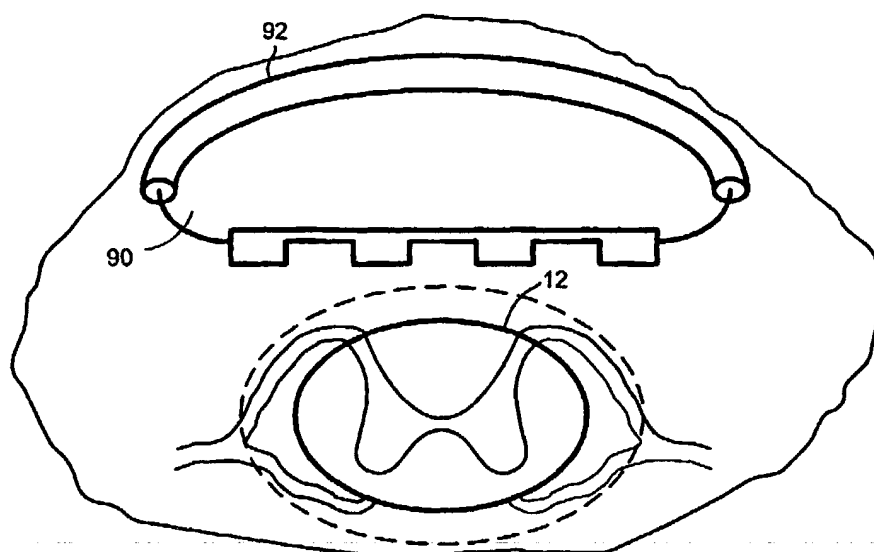
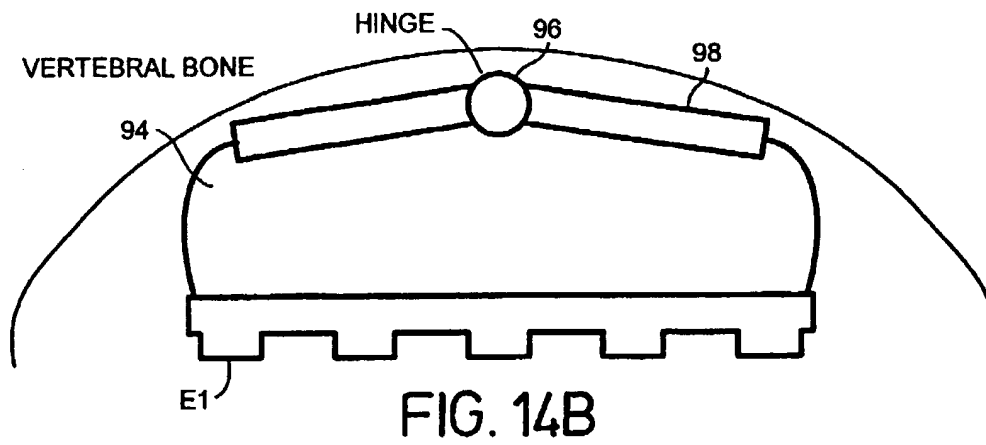
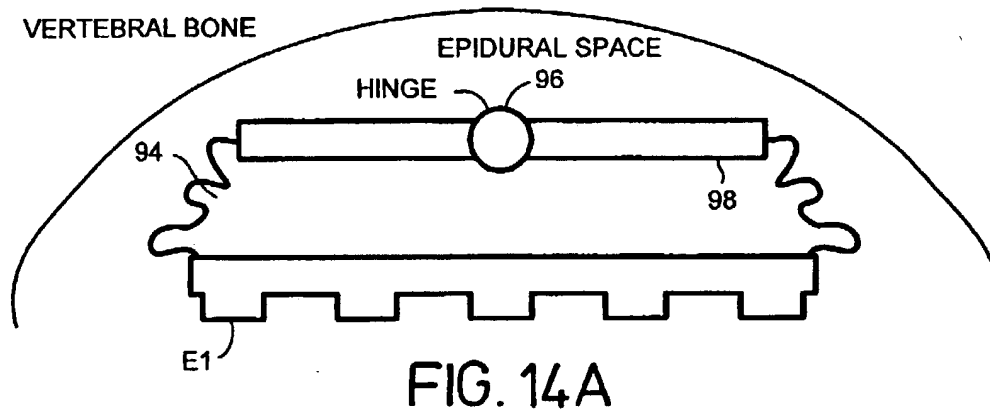


FIG. 13B



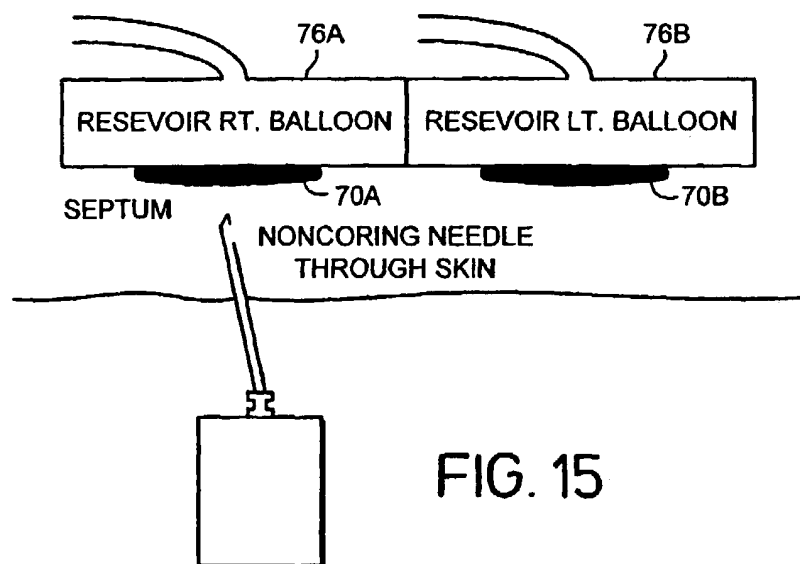


FIG. 15

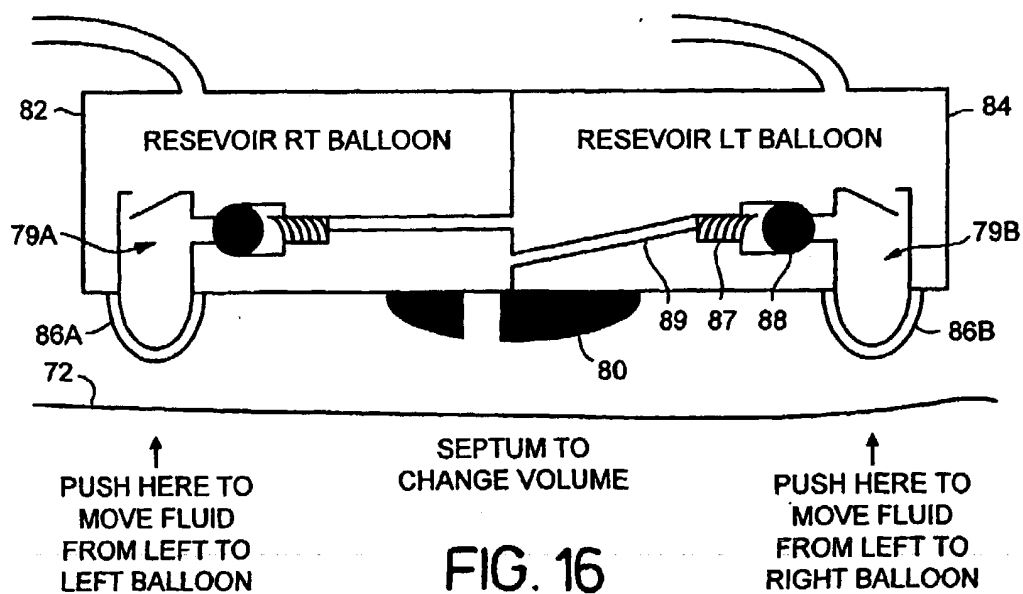


FIG. 16

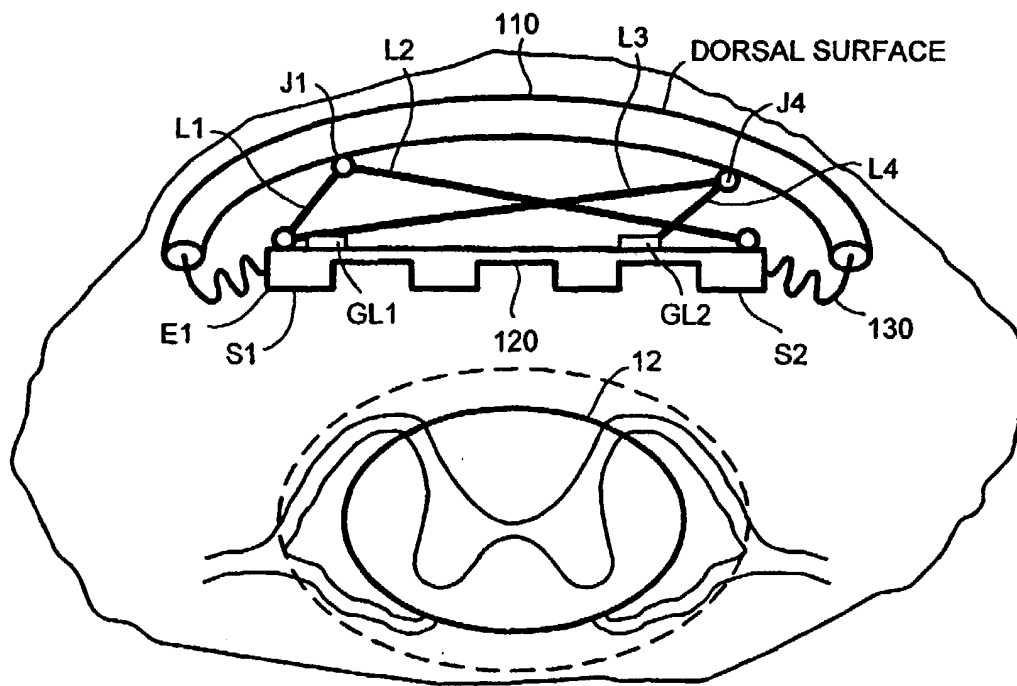


FIG. 17A

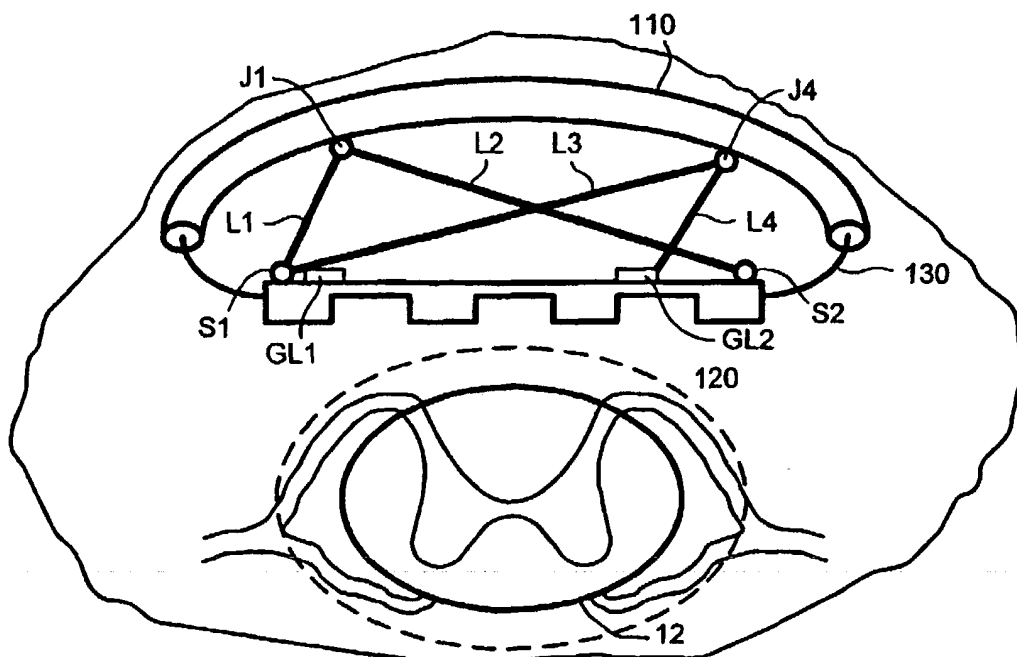
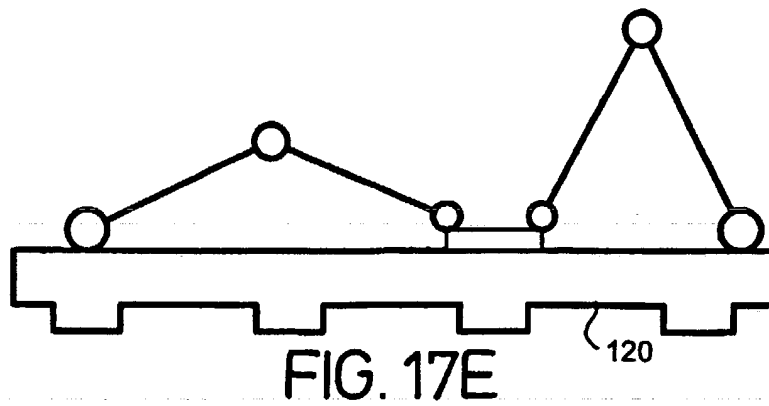
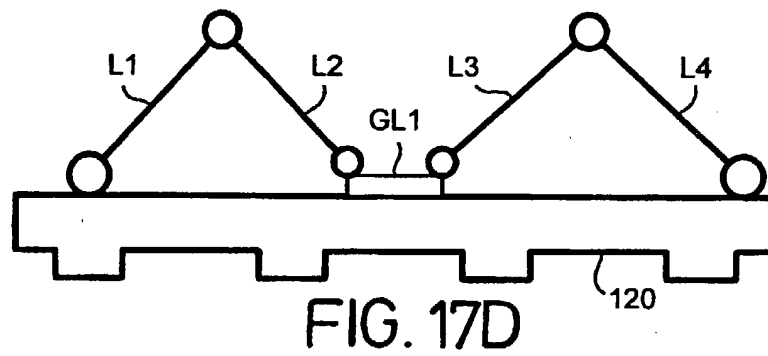
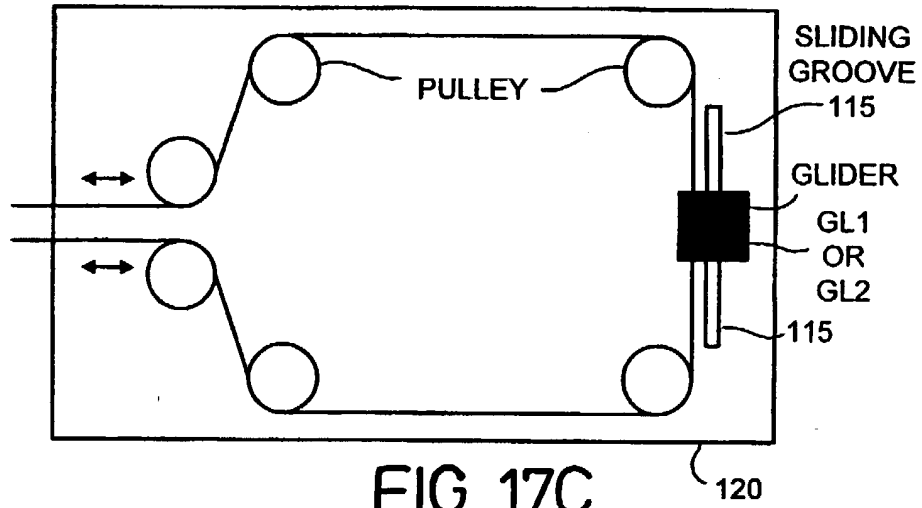


FIG. 17B



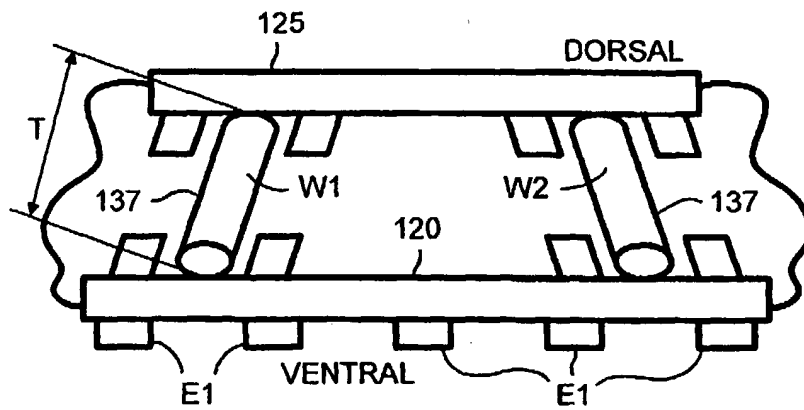


FIG. 18A

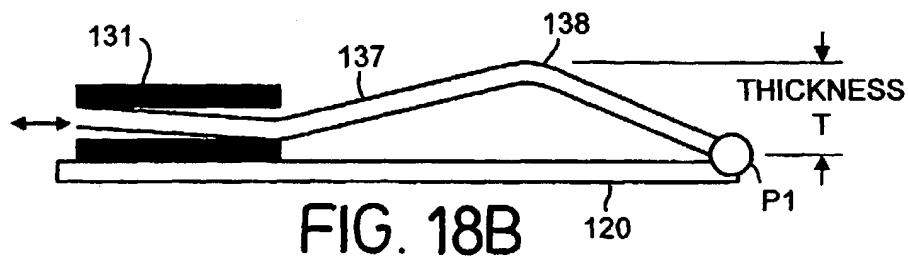


FIG. 18B

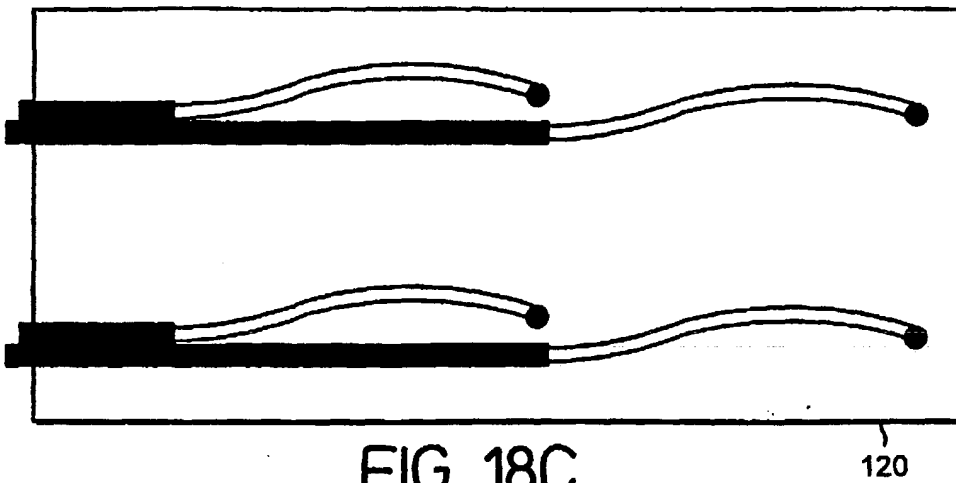


FIG. 18C

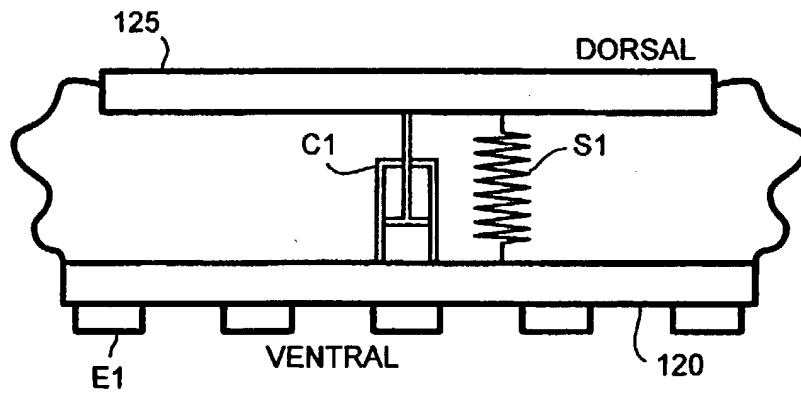


FIG. 19

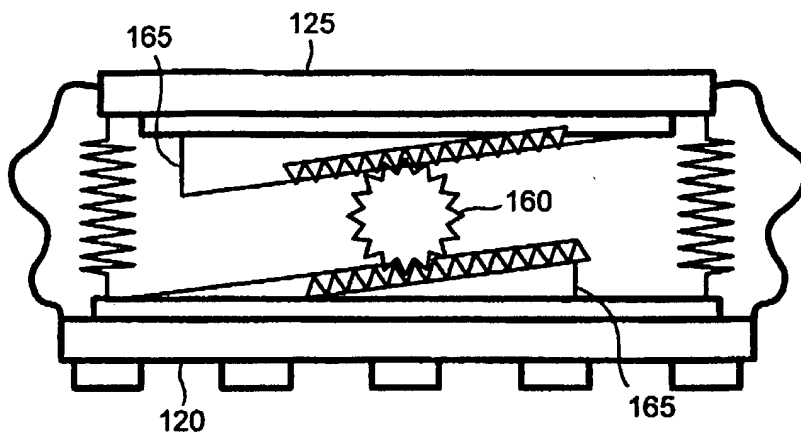


FIG. 20

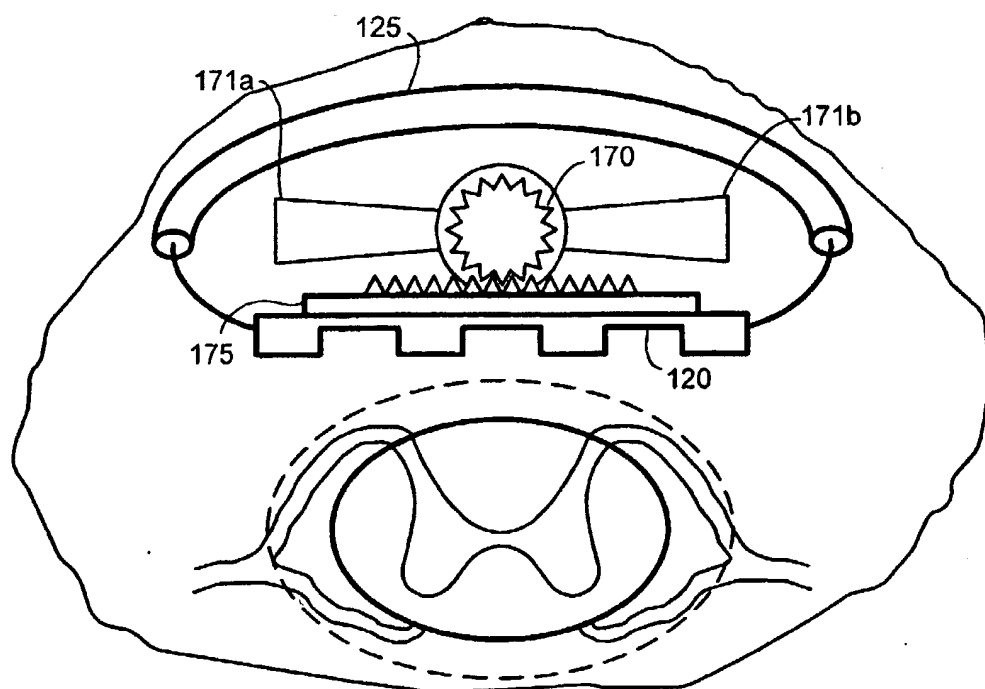


FIG. 21A

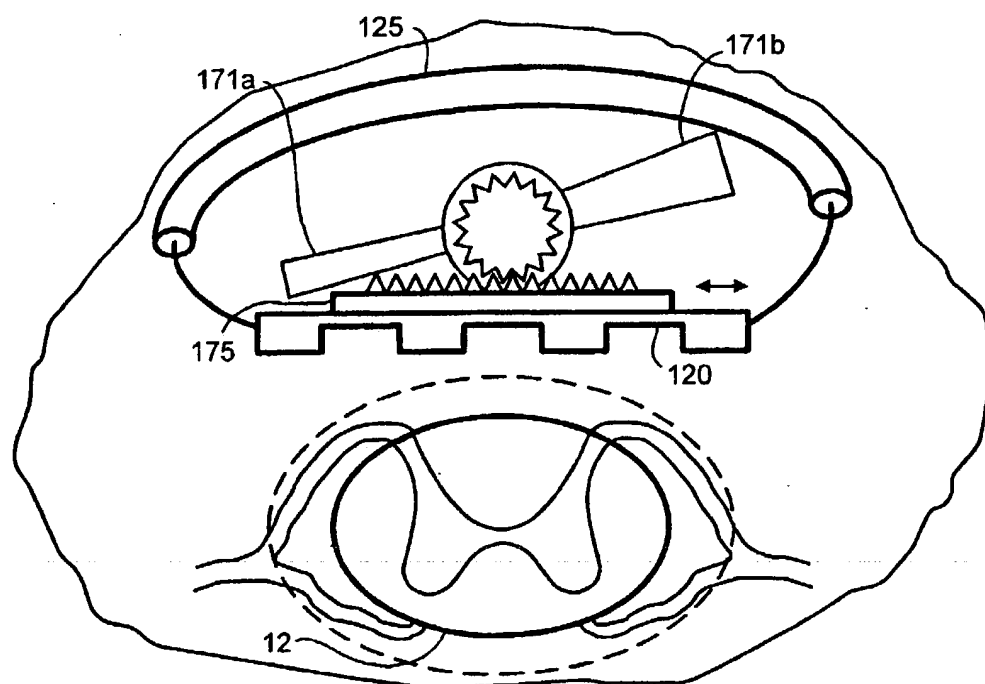


FIG. 21B



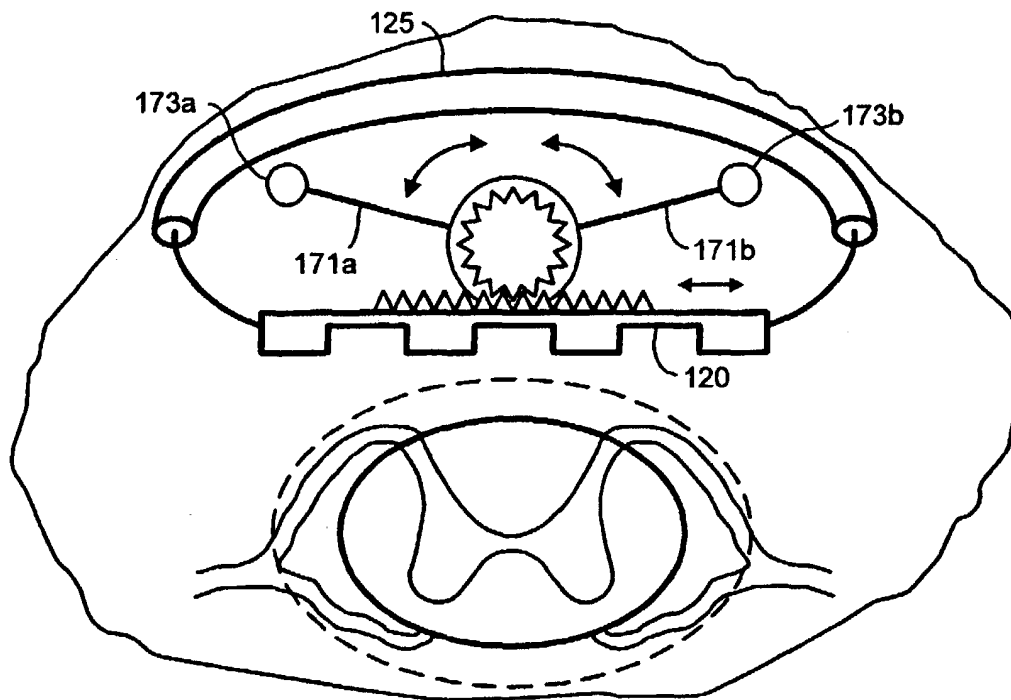


FIG. 21C

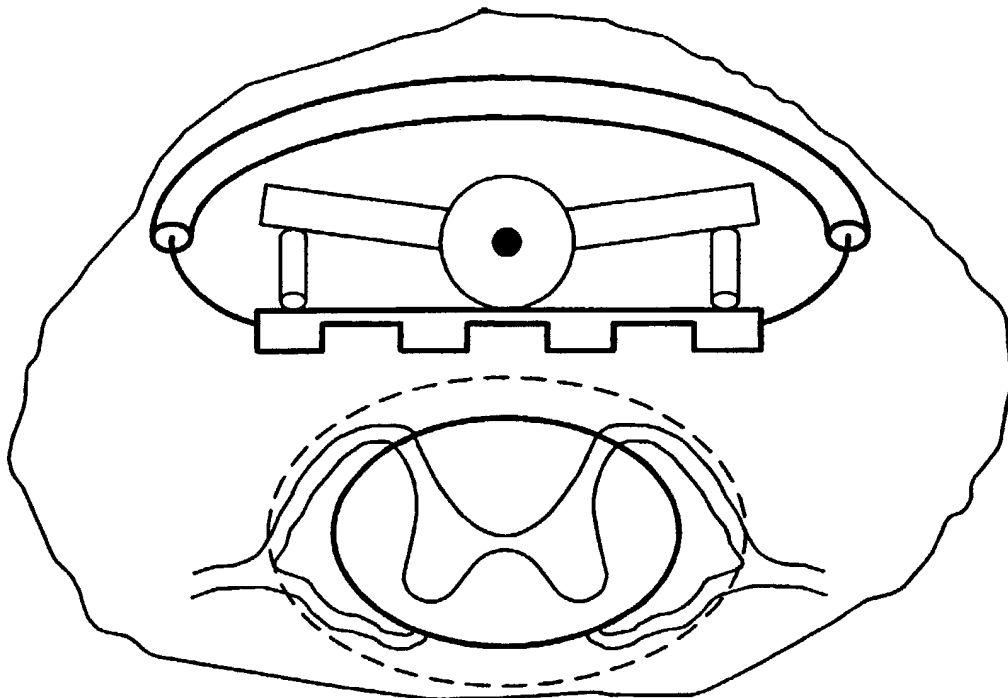


FIG. 22

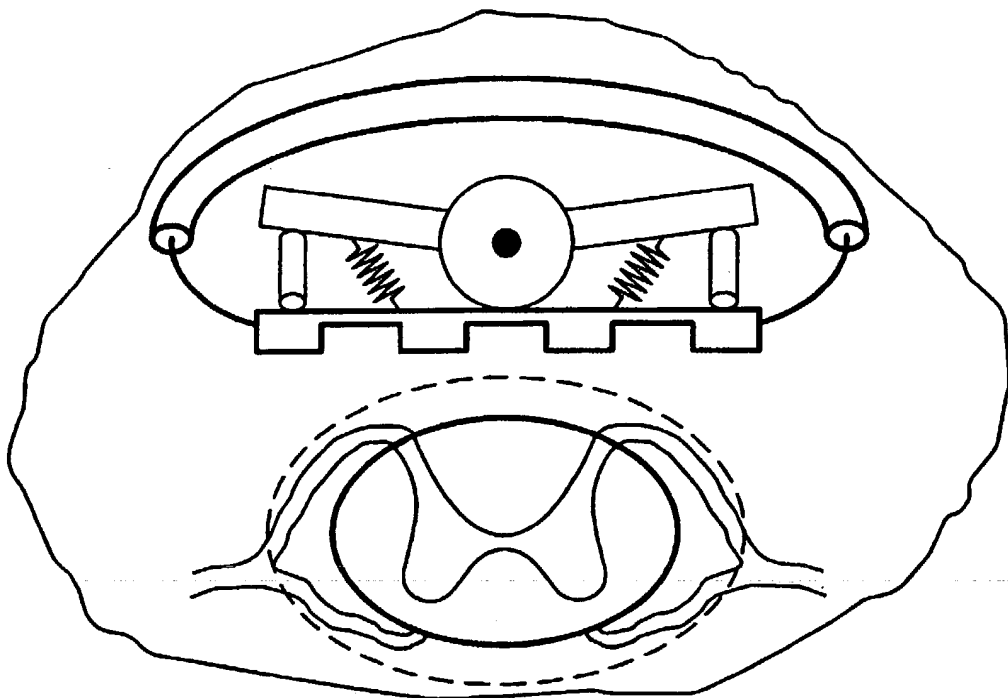


FIG. 23

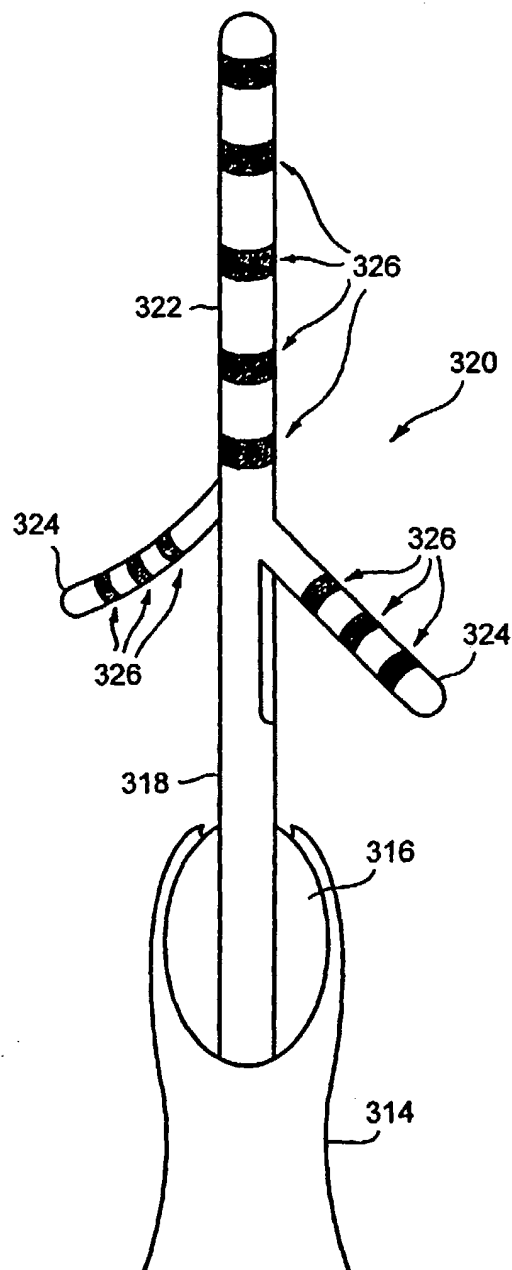


FIG. 24

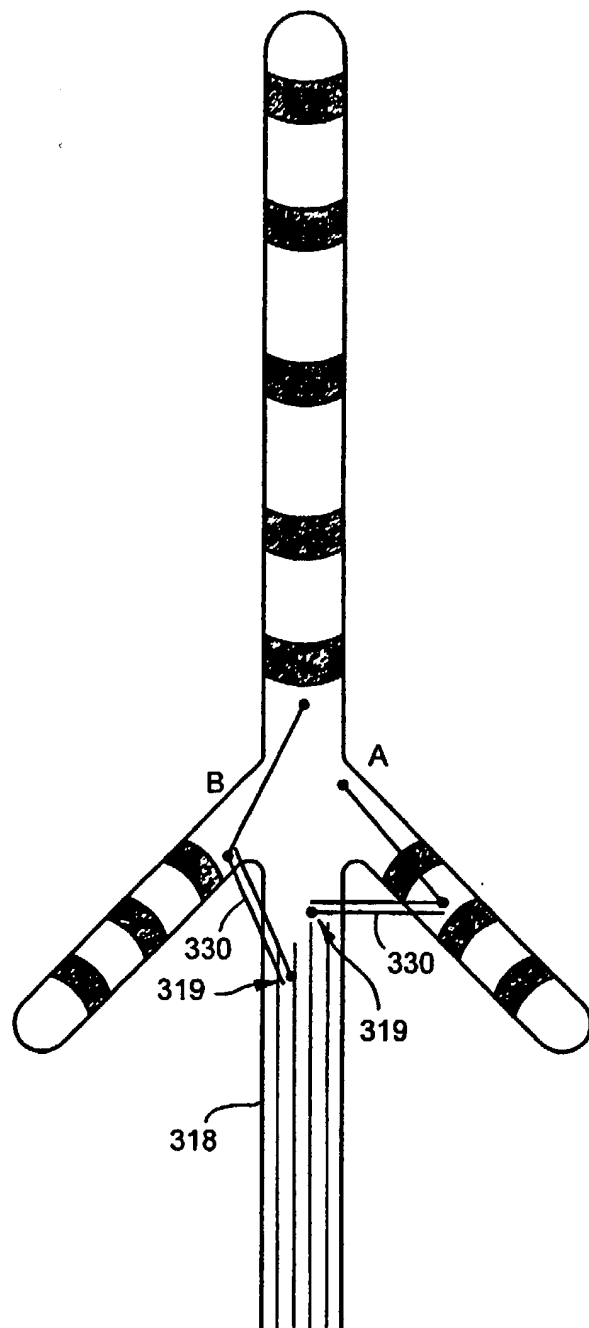


FIG. 25

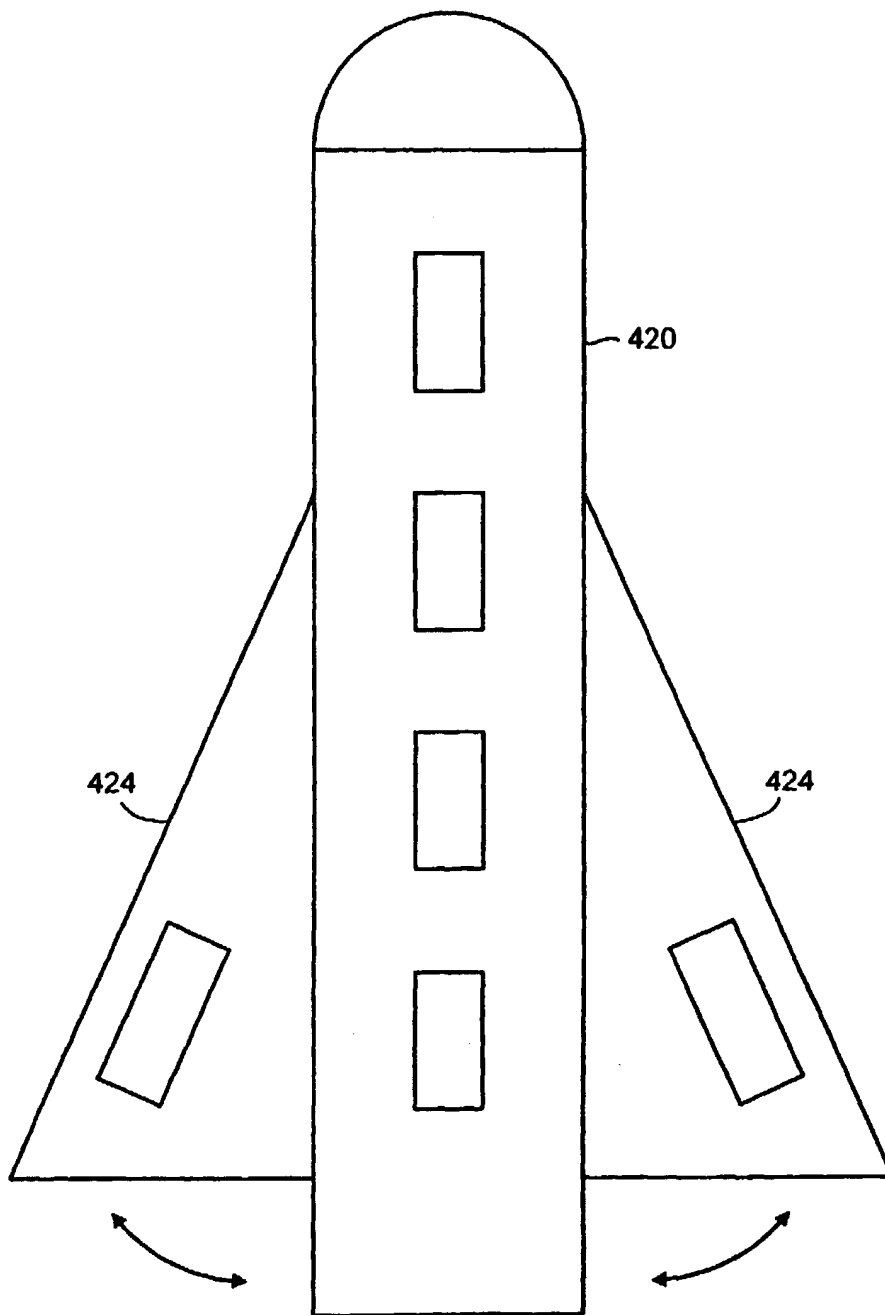


FIG. 26

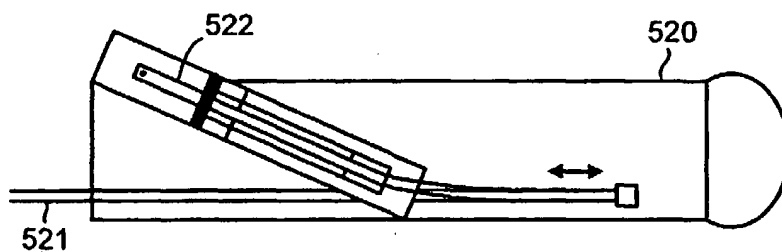


FIG. 27A

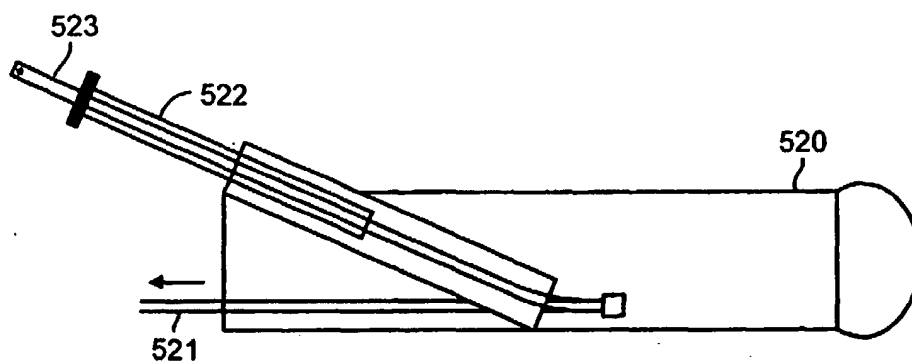
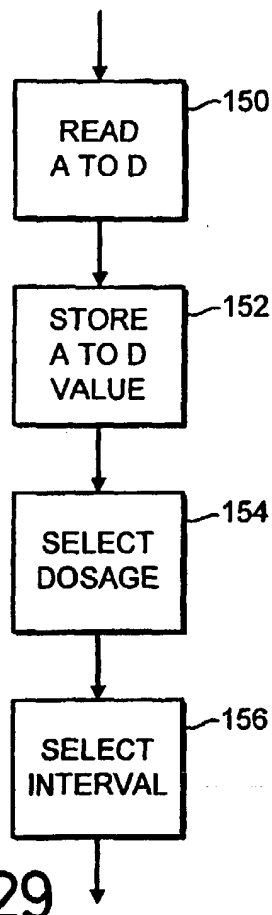
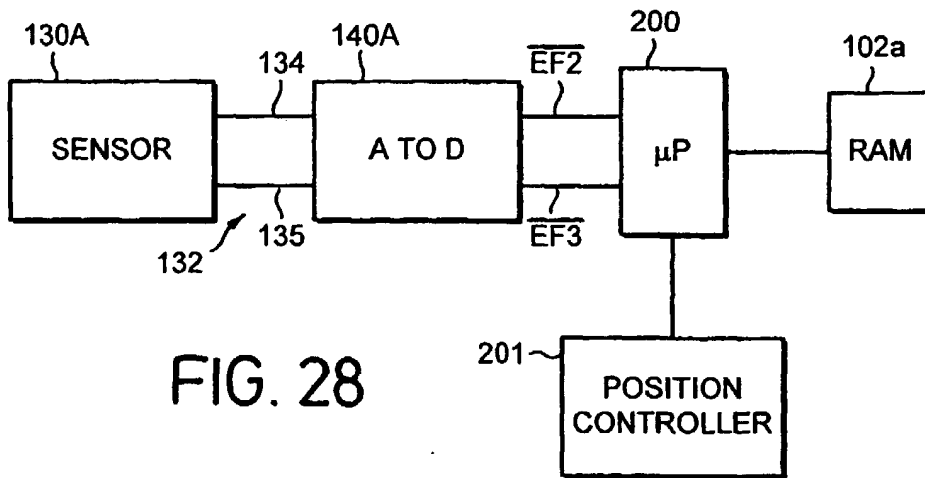
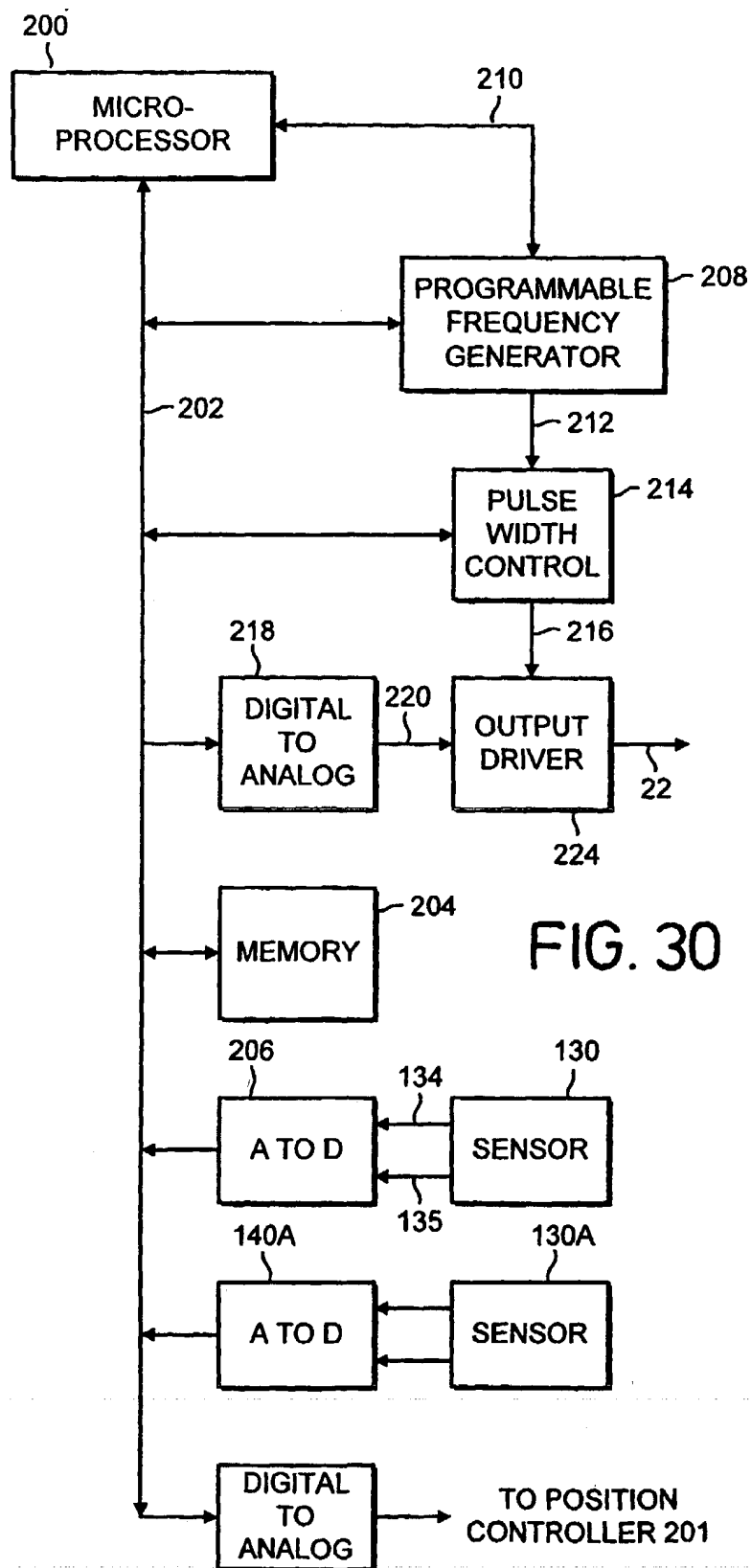


FIG. 27B







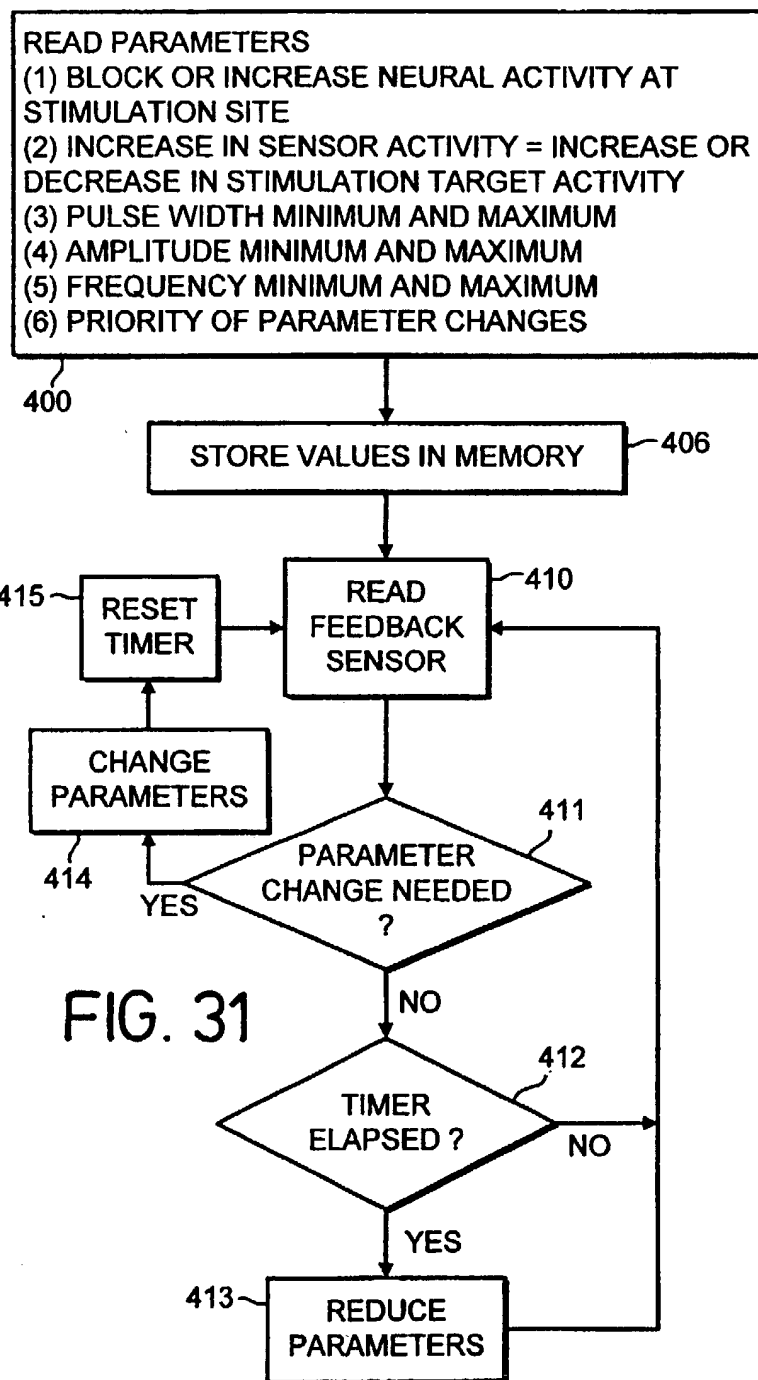
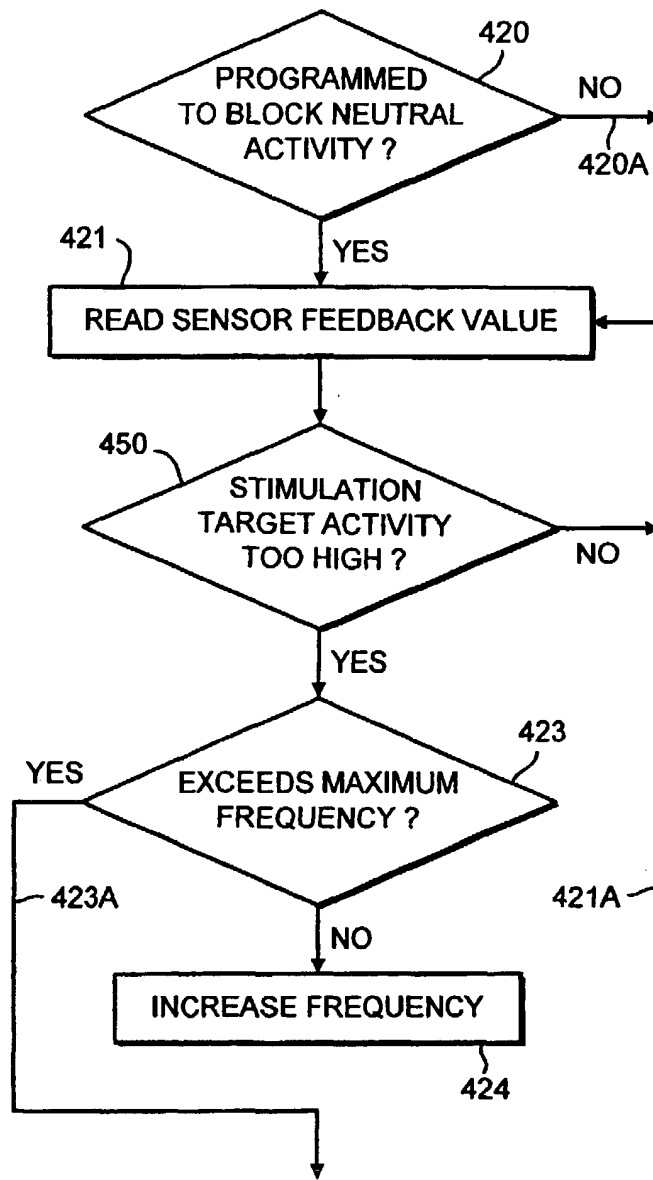


FIG. 32



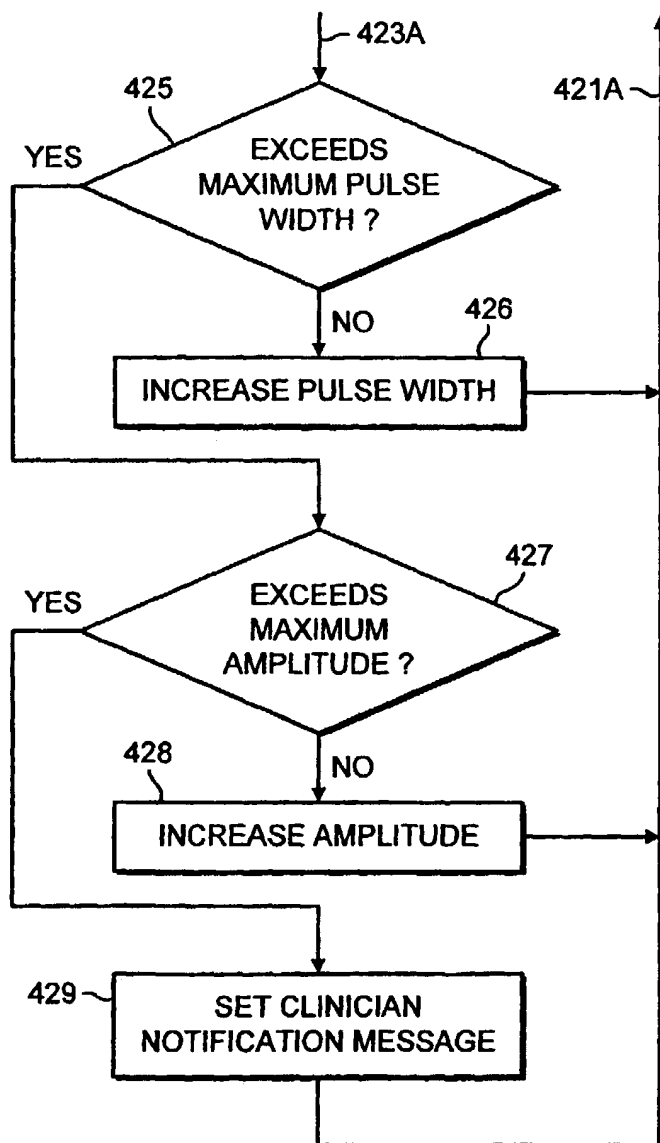
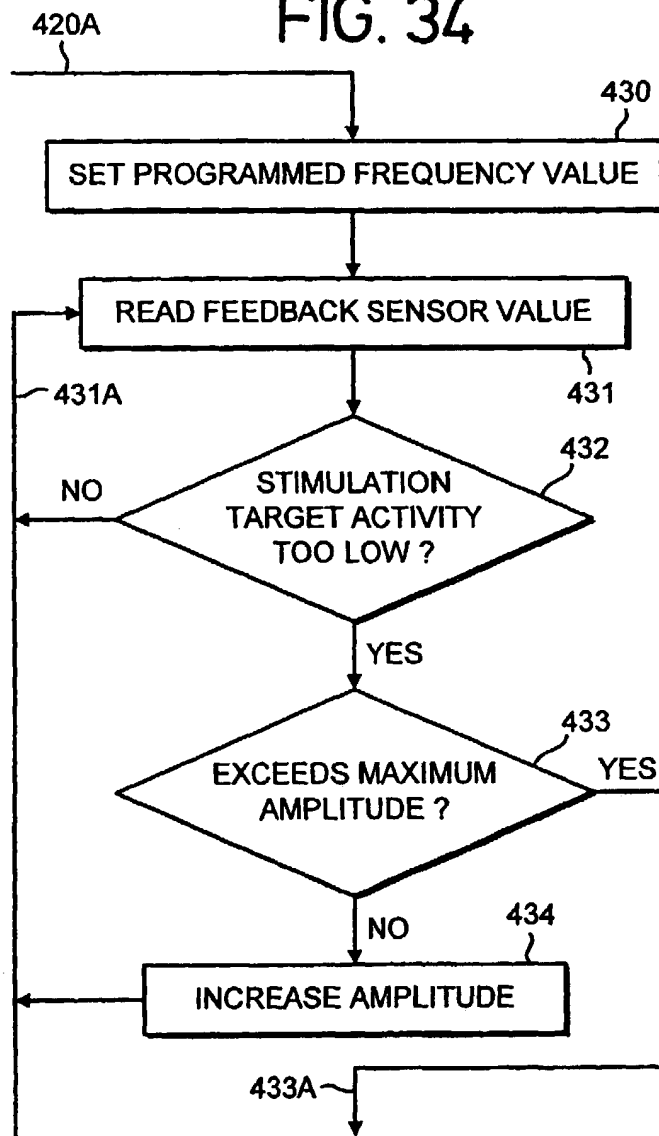


FIG. 33

FIG. 34



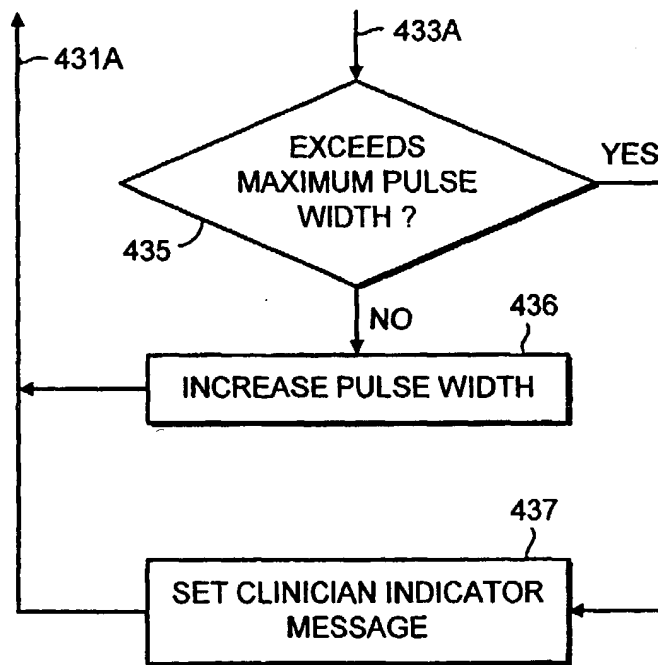


FIG. 35

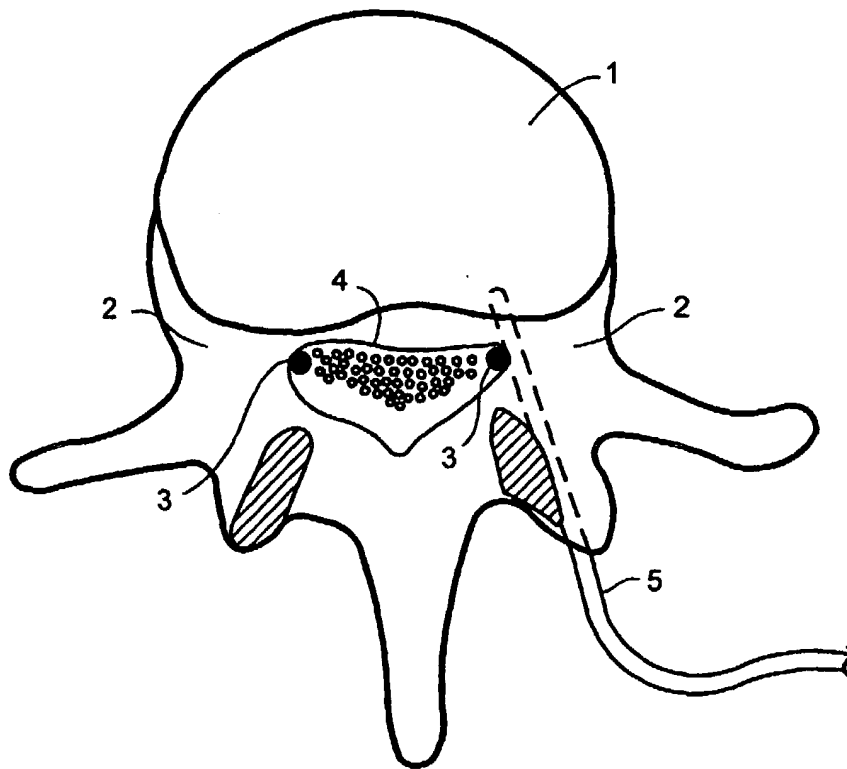


FIG. 36A

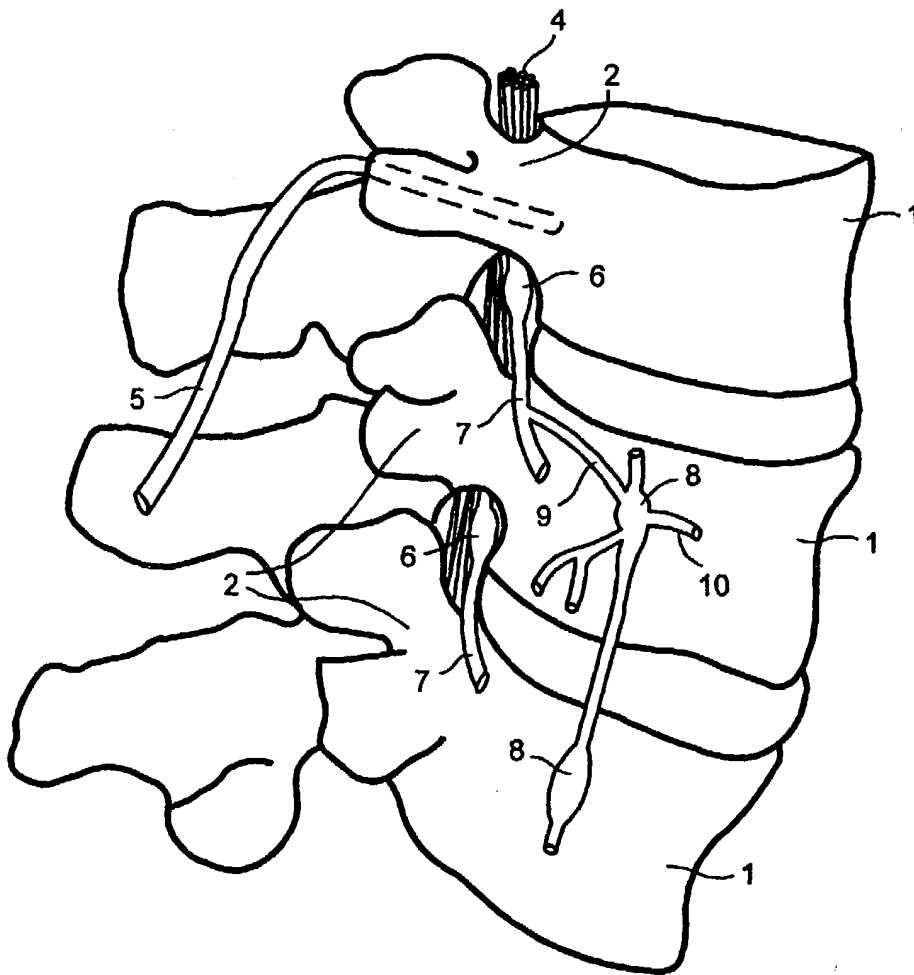


FIG. 36B

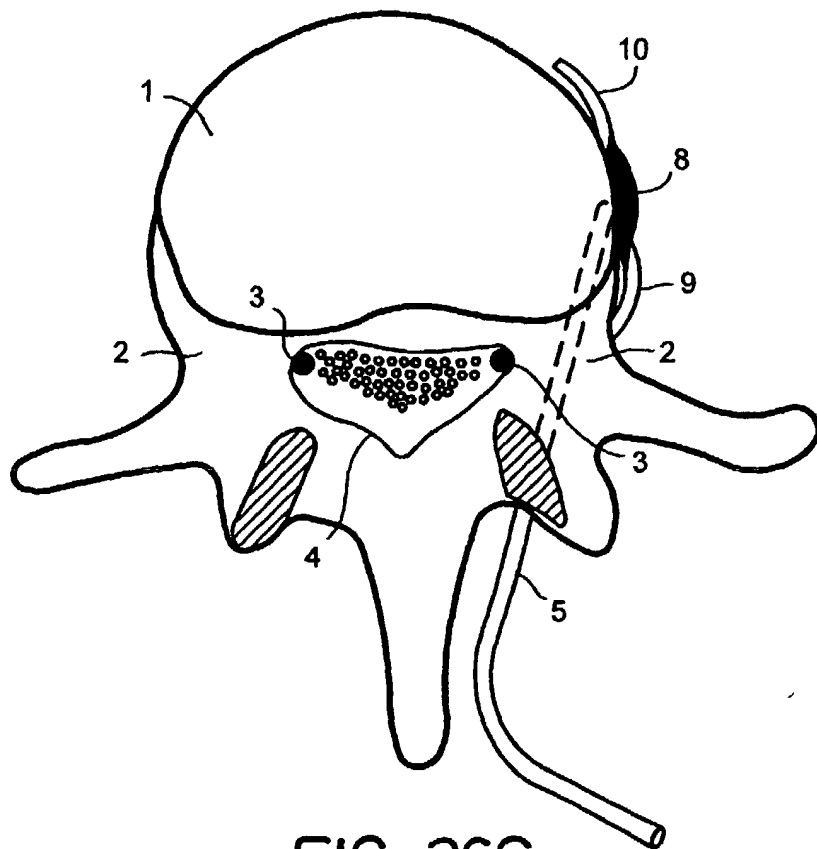


FIG. 36C



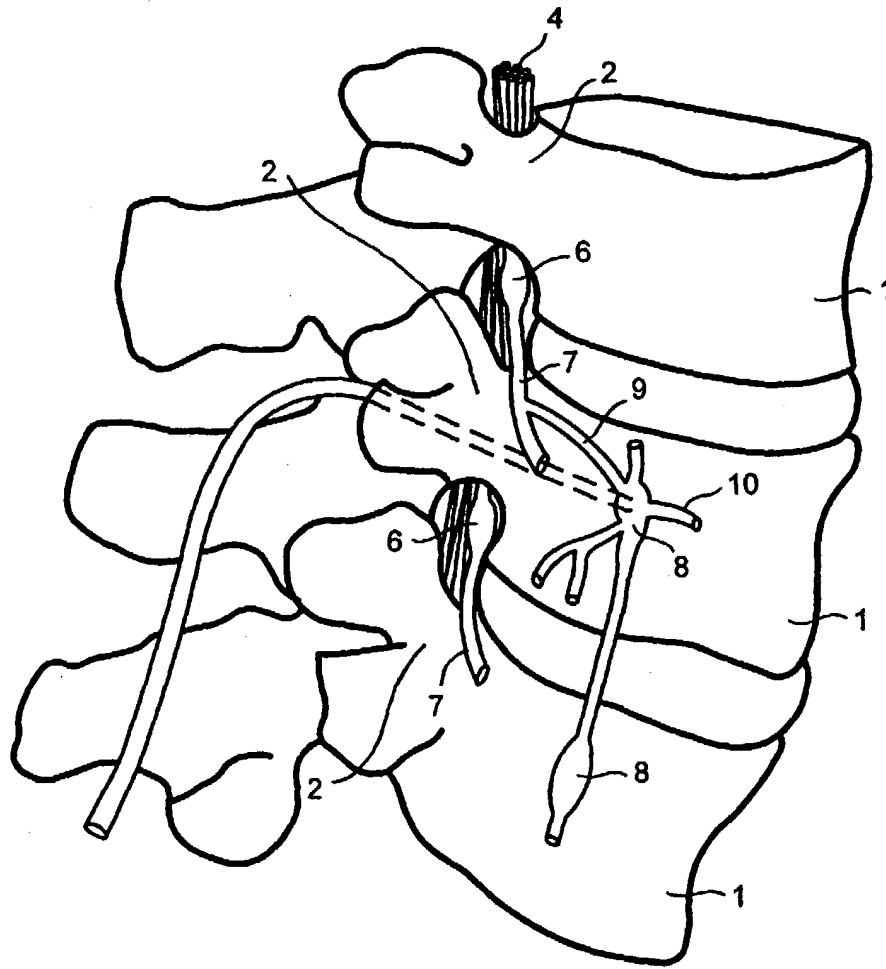
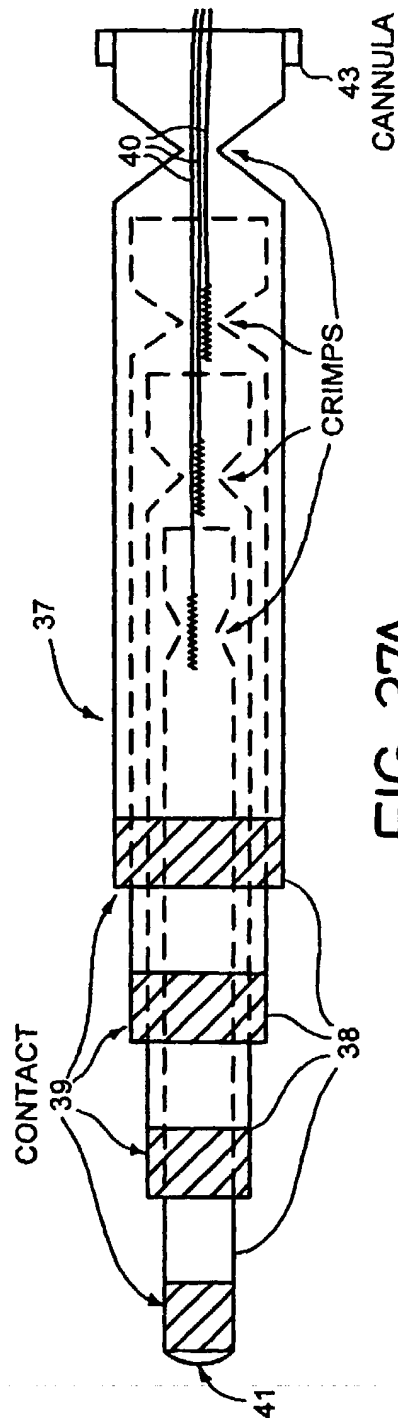


FIG. 36D



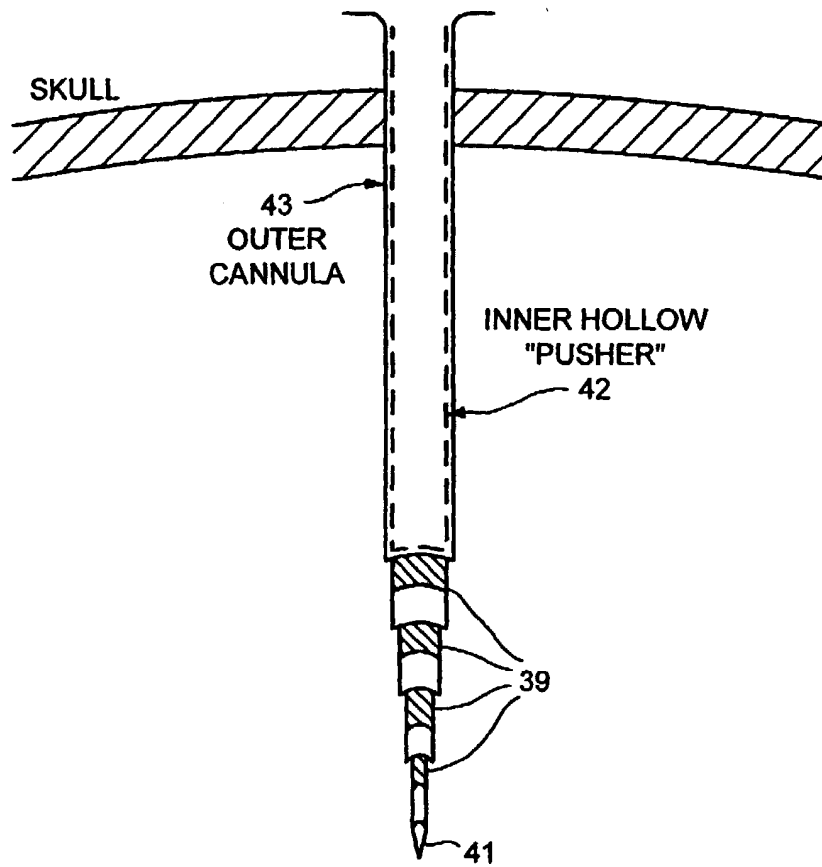


FIG. 37B

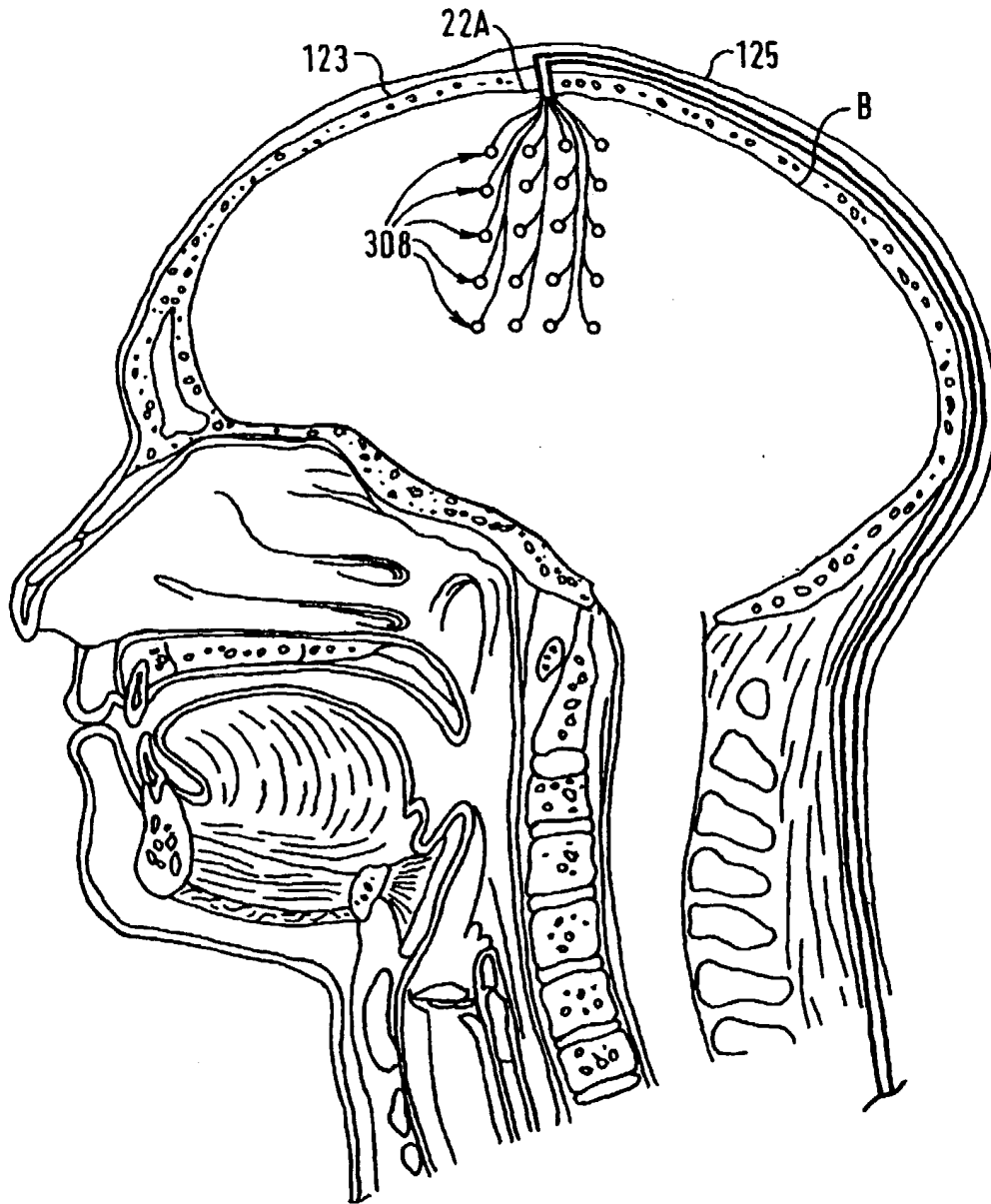


FIG. 38A

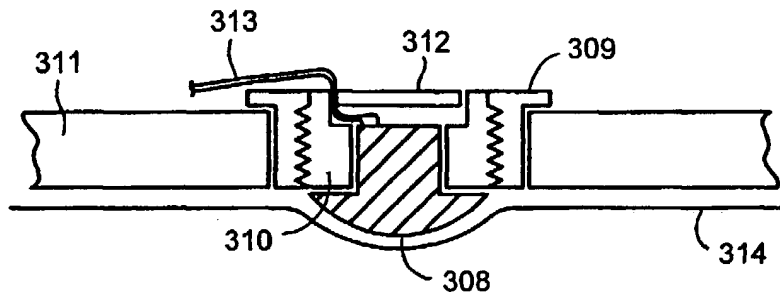


FIG. 38B

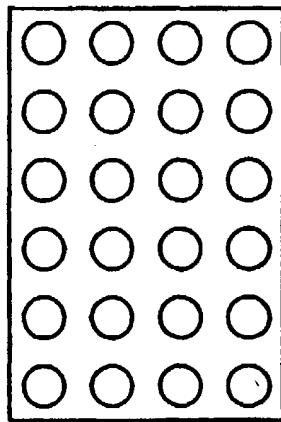


FIG. 38C

(19)



Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11)

**EP 1 048 317 A3**

(12)

## EUROPEAN PATENT APPLICATION

(88) Date of publication A3:  
19.03.2003 Bulletin 2003/12

(51) Int Cl.7: **A61N 1/05, A61N 1/34**

(43) Date of publication A2:  
02.11.2000 Bulletin 2000/44

(21) Application number: **00107043.2**

(22) Date of filing: **03.04.2000**

(84) Designated Contracting States:  
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE**  
Designated Extension States:  
**AL LT LV MK RO SI**

(30) Priority: **30.04.1999 US 303145**

(71) Applicant: **MEDTRONIC, INC.**  
**Minneapolis, Minnesota 55432-3576 (US)**

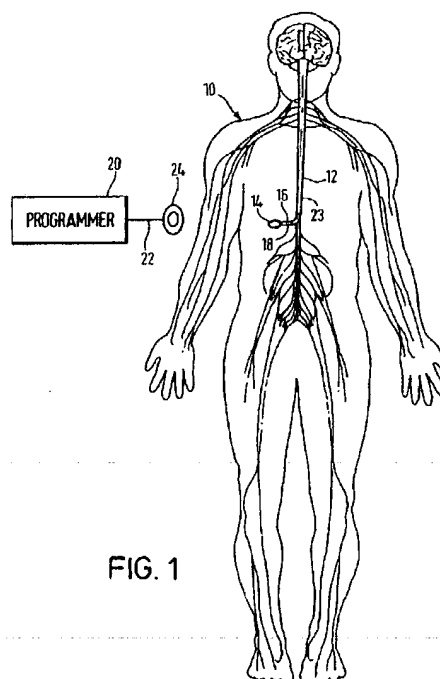
(72) Inventors:  
• **Gielen, Frans**  
**6251 NE Eckelrade (NL)**  
• **King, Gary W.**  
**Fridley, Minnesota 55432 (US)**

- **Petersen, Daryle**  
**Minneapolis, Minnesota 55421 (US)**
- **Rise, Mark T.**  
**Monticello, Minnesota 55362 (US)**
- **Schendel, Michael**  
**Andover, Minnesota 55304 (US)**
- **Starkebaum, Warren**  
**Plymouth, Minnesota 55441 (US)**

(74) Representative: **Hughes, Andrea Michelle**  
**Frank B. Dehn & Co.,**  
**European Patent Attorneys,**  
**179 Queen Victoria Street**  
**London EC4V 4EL (GB)**

(54) **Systems for positioning therapy delivery elements within a spinal cord or a brain**

(57) The present invention addresses the problems associated with lead migration, patient movement or position, histological changes, neural plasticity or disease progression. The present invention discloses techniques for implanting a lead having therapy delivery elements, such as electrodes or drug delivery ports, within a vertebral or cranial bone so as to maintain these elements in a fixed position relative to a desired treatment site. The therapy delivery elements may thereafter be adjusted in situ with a position control mechanism and/or a position controller to improve the desired treatment therapy. The present invention also discloses techniques for non-invasively positioning and re-positioning therapy delivery elements after implant to provide electrical stimulation and/or drug infusion to a precise target. A position control mechanism and/or a position controller are provided for adjusting in situ the position of the therapy delivery elements relative to the targeted tissue of interest. The therapy delivery elements may be positioned laterally in any direction relative to the targeted treatment site or toward or away from the targeted treatment site. A control system may be provided for open- or closed-loop feedback control of the position of the therapy delivery elements as well as other aspects of the treatment therapy.



**FIG. 1**

**EP 1 048 317 A3**



European Patent  
Office

# EUROPEAN SEARCH REPORT

Application Number  
EP 00 10 7043

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	EP 0 104 287 A (SCARBERRY EUGENE NELSON) 4 April 1984 (1984-04-04) * figures 1,4 *	1	A61N1/05 A61N1/34
Y	---	6	
X	US 4 285 347 A (HESS STANLEY R) 25 August 1981 (1981-08-25) * figures 1-4 *	1	
Y	---	6	
X	US 4 519 403 A (DICKHUDT EUGENE A) 28 May 1985 (1985-05-28) * figures 1,2 *	1	
Y	---	6	
X,P	WO 99 55411 A (MEDTRONIC INC) 4 November 1999 (1999-11-04) * abstract *	1-5,7	
Y	---	6	
Y	US 5 683 422 A (RISE MARK T) 4 November 1997 (1997-11-04) * abstract *	6	
	-----		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61N
The present search report has been drawn up for all claims			
Place of search <b>MUNICH</b>		Date of completion of the search <b>22 January 2003</b>	Examiner <b>Rodríguez Cossío, J</b>
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			

EPO FORM 1503 03/02 (P04001)



European Patent  
Office

Application Number

EP 00 10 7043

#### CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

- ☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):
- ☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

#### LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

- ☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.
- ☒ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.
- ☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:
- ☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:





European Patent  
Office

LACK OF UNITY OF INVENTION  
SHEET B

Application Number  
EP 00 10 7043

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-18  
position control mechanism
2. Claims: 19-26,18  
extendable member depending from a central portion
3. Claims: 27,28  
bone implantable housing member
4. Claims: 29-32,8-11  
mechanism for expanding the middle portion of a paddle lead
5. Claims: 33-35,12-14  
balloon-like mechanism
6. Claims: 36-38,15  
movable means on ventral side
7. Claims: 39,17  
gear means
8. Claim : 16  
wire means

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 00 10 7043

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
The members are as contained in the European Patent Office EDP file on  
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

22-01-2003

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0104287	A	04-04-1984	US 4351330 A	28-09-1982
			EP 0104287 A1	04-04-1984
US 4285347	A	25-08-1981	EP 0023410 A1	04-02-1981
US 4519403	A	28-05-1985	NONE	
WO 9955411	A	04-11-1999	US 6161047 A	12-12-2000
			EP 1075303 A2	14-02-2001
			WO 9955411 A2	04-11-1999
			US 2002151948 A1	17-10-2002
			US 6319241 B1	20-11-2001
			US 6292702 B1	18-09-2001
			US 2001023367 A1	20-09-2001
			US 2001053885 A1	20-12-2001
US 5683422	A	04-11-1997	AU 2595397 A	12-11-1997
			EP 0895483 A1	10-02-1999
			WO 9739795 A1	30-10-1997
			US 5792186 A	11-08-1998

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82